

1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

3

4 WITNESS: DIRECT CROSS REDIRECT RECROSS

5 Freese 4940 4991 5005

6 Kralovec 5007 5066 5104 5108

7 5109 5110

8 Gould 5112 5161 5176

9 Clark 5184

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11 EXHIBITS FOR ID IN EVID

12 Commission

13 None

14 Schering

15 None

16 Upsher

17 Number 308 4982

18 Number 311 4970

19 Number 329 4960

20 Number 333 4967

21 Number 367 5151

22 Number 452 5051

23 Number 539 4976

24 Number 711 5187

25 Number 732 5053

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1	Upsher	
2	Number 812	5144
3	Number 1553	5140
4	Number 1558	5187
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6	OTHER EXHIBITS REFERENCED	PAGE
7	Commission	
8	CX 261	5168
9	CX 266	5164
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15	USX 132	5078
16	USX 374	5150
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For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 FEDERAL TRADE COMMISSION

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3 In the Matter of:)

4 SCHERING-PLOUGH CORPORATION,)

5 a corporation,)

6 and)

7 UPSHER-SMITH LABORATORIES,) File No. D09297

8 a corporation,)

9 and)

10 AMERICAN HOME PRODUCTS,)

11 a corporation.)

12 -----)

13

14 Friday, February 22, 2002

15 9:30 a.m.

16 TRIAL VOLUME 21

17 PART 1

18 PUBLIC RECORD

19 BEFORE THE HONORABLE D. MICHAEL CHAPPELL

20 Administrative Law Judge

21 Federal Trade Commission

22 600 Pennsylvania Avenue, N.W.

23 Washington, D.C.

24

25 Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

2 - - - - -

3 JUDGE CHAPPELL: All right, let's reconvene
4 docket 9297.

5 Mr. Curran?

6 MR. CURRAN: Yes, Your Honor, Upsher-Smith is
7 ready to call our next witness if you're ready.

8 JUDGE CHAPPELL: Let's go.

9 MR. CURRAN: At this time we call Lori Freese
10 of Upsher-Smith, and my colleague Jaime Crowe will
11 handle this witness.

12 JUDGE CHAPPELL: Okay.

13 Raise your right hand, please.

14 Whereupon--

15 LORI M. FREESE

16 a witness, called for examination, having been first
17 duly sworn, was examined and testified as follows:

18 JUDGE CHAPPELL: Thank you, have a seat.

19 State your full name for the record, please.

20 THE WITNESS: My name is Lori Michelle Freese.

21 MS. BOKAT: Excuse me, Your Honor, we seem to
22 have lost our realtime connection here.

23 (Discussion off the record.)

24 DIRECT EXAMINATION

25 BY MR. CROWE:

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1 Q. Good morning, Ms. Freese.

2 A. Good morning.

3 Q. Ms. Freese, are you employed at Upsher-Smith?

4 A. Yes, I am.

5 Q. What position do you currently hold?

6 A. I am the manager of the professional services
7 department.

8 Q. When did you first start working at
9 Upsher-Smith?

10 A. I started in December of 1993.

11 Q. And what position did you start in?

12 A. Professional services associate.

13 Q. What kinds of qualifications were required for
14 the professional services associate position?

15 A. The job description required that I be a
16 licensed pharmacist in the State of Minnesota.

17 Q. All right, let's discuss your educational
18 background and training then for just a moment.

19 Do you have a college degree?

20 A. Yes.

21 Q. Where from?

22 A. From the University of Minnesota. I have a
23 Bachelor's of Science degree in pharmacy.

24 Q. When did you graduate?

25 A. I graduated in May of 1991.

1 Q. What did you do after your graduation?

2 A. I prepared for my licensure examination to
3 become licensed as a pharmacist in Minnesota.

4 Q. Did you take the exam?

5 A. Yes.

6 Q. Did you pass the exam?

7 A. Yes.

8 Q. And did you become a licensed pharmacist in
9 Minnesota?

10 A. Yes.

11 Q. All right. What was the first job that you
12 held after you became a licensed pharmacist?

13 A. I accepted a position at Mercy Hospital, which
14 is in Coon Rapids, Minnesota.

15 Q. And what position did you hold at Mercy
16 Hospital?

17 A. Staff pharmacist.

18 Q. What were your responsibilities?

19 A. I monitored patients' drug therapy, dispensed
20 medications and supervised the pharmacy technician
21 staff.

22 Q. Now, you said that among other things you
23 dispensed medications. Is that the same thing as
24 filling prescriptions?

25 A. Yes. In a hospital, it's a little bit

1 different than in a retail setting, but it's basically
2 filling prescriptions for hospitalized patients.

3 Q. What was the next job that you held?

4 A. I then accepted a position at United Pharmacy
5 Associates in Golden Valley, Minnesota, and that is a
6 pharmacy that services patients in nursing homes or
7 long-term care facilities.

8 Q. Can we call that UPA?

9 A. Yes.

10 Q. When did you start at UPA?

11 A. I started in early 1992.

12 Q. And what position did you hold there?

13 A. Again, staff pharmacist.

14 Q. What responsibilities did you have?

15 A. Filling prescriptions and supervising the
16 pharmacy technician staff as well as helping to
17 implement an intravenous drug program.

18 Q. What was the next job that you held after UPA?

19 A. I then accepted the position at Upsher-Smith in
20 December of 1993.

21 Q. So, how long were you at UPA before you started
22 at Upsher-Smith?

23 A. I worked there for approximately a year and a
24 half as a full-time pharmacist, and then after I
25 accepted my position at Upsher-Smith, I did still work

1 occasionally on Saturdays or evenings.

2 Q. So, you started at Upsher-Smith in December of
3 1993?

4 A. Yes.

5 Q. As a professional services associate?

6 A. Yes.

7 Q. What responsibilities did you have as a
8 professional services associate?

9 A. I was responsible for answering drug
10 information questions that the company would get from
11 physicians or other health professionals, questions
12 that we would get from consumers regarding our
13 products, as well as internal questions that we might
14 work from our representatives.

15 Q. So, among other things, you would answer
16 questions from doctors or patients?

17 A. Yes.

18 Q. Did you have to be familiar with Upsher-Smith's
19 line of pharmaceutical products?

20 A. Yes.

21 Q. Did you train new employees with respect to
22 Upsher-Smith's line of pharmaceutical products?

23 A. Yes. One of my main responsibilities in
24 addition to fielding questions was to complete the
25 technical training for representatives, which really

1 entailed providing them with background information on
2 the disease states that our products are used in, other
3 products that would compete with our products, making
4 sure that they had that medical background so that they
5 could discuss our products with physicians.

6 Q. And did you train Upsher-Smith employees on the
7 entire line of Upsher-Smith pharmaceutical products?

8 A. Yes, for all of the products that we would
9 promote, I would train the representatives.

10 Q. Did you have to keep abreast of the medical
11 literature as part of your responsibilities?

12 A. Yes, I would monitor the medical literature and
13 continue to monitor the medical literature in all of
14 the therapeutic areas where Upsher-Smith has products.

15 Q. And what kind of medical literature are you
16 referring to?

17 A. I would review medical journals. I would
18 attend medical meetings so that I could attend
19 presentations that physicians would give in those
20 areas. I'd talk with physicians who treat patients in
21 those areas on a regular basis.

22 JUDGE CHAPPELL: Excuse me, Mr. Crowe, the
23 restart worked on my computer. My CaseView is now
24 working.

25 MR. KLEIN: Mine is as well.

1 JUDGE CHAPPELL: Oh, we are all online? Thank
2 you.

3 MR. CROWE: Thank you, Your Honor.

4 BY MR. CROWE:

5 Q. What particular pharmaceutical products or
6 disease states did you track?

7 A. Upsher-Smith has a number of cardiovascular
8 products, so I would pay particular attention, and in
9 that category we have some products in dermatology, so
10 I would also keep track of that therapeutic area.

11 Q. Did you have another position at Upsher-Smith
12 after professional services associate?

13 A. Yes. In the middle of 1995, I was promoted to
14 professional services coordinator.

15 Q. And did you have the same responsibilities as
16 professional services coordinator that you did as a
17 professional services associate?

18 A. Yes, I did, and in addition to that, I also
19 supervised another pharmacist in my department at that
20 point.

21 Q. Did you have another position at Upsher-Smith
22 after professional services coordinator?

23 A. Yes, then I was later promoted to professional
24 services supervisor, and that was toward the end of '96
25 or early '97.

1 Q. And again, did you have the same
2 responsibilities as a supervisor that you did as a
3 coordinator?

4 A. Yes, I had all of the same responsibilities,
5 perhaps more in an oversight manner, and then I did
6 begin to take out additional responsibilities as well.
7 I began to more frequently accompany representatives if
8 they called on physicians or large influential
9 accounts, and then I also accepted some
10 responsibilities in our new business development area
11 with Vickie O'Neill toward the beginning of 1997.

12 Q. And can you describe those responsibilities
13 briefly for us?

14 A. Yes. When Upsher-Smith reviews or evaluates a
15 potential new product, I would complete an overview of
16 the disease state that that product was used in and an
17 overview of other products that compete with that or
18 that would compete with that product so that we could
19 get a sense of how this new product would be positioned
20 in that therapeutic area.

21 Q. What was the next position that you held at
22 Upsher-Smith?

23 A. Then in the -- toward the middle of 1998, I was
24 promoted to professional services manager, and that's
25 the position that I still hold today.

1 Q. Let me ask you, did you have the same or do you
2 have the same responsibilities as a manager that you
3 did as a supervisor?

4 A. Yes, I supervise the same department or manage
5 the same department, so I have essentially the same
6 responsibilities.

7 Q. And are you still responsible for training new
8 Upsher-Smith employees?

9 A. Yes.

10 Q. And do you still keep up to date with the
11 medical literature with respect to the line of
12 pharmaceutical products that Upsher-Smith has
13 available?

14 A. Yes.

15 Q. And the disease states that are relevant to
16 those drugs?

17 A. Yes.

18 Q. Who do you report to at Upsher-Smith?

19 A. I report to Phil Dritsas.

20 Q. Ms. Freese, does Upsher-Smith have a line of
21 potassium products?

22 A. Yes.

23 Q. And can you tell us what products Upsher-Smith
24 has available?

25 A. Yes, Upsher-Smith has a line of potassium

1 products with the name Klor Con. We have Klor Con 20
2 mEq and 25 mEq powder, Klor Con 25 mEq effervescent
3 tablets, Klor Con 8 and 10 wax matrix tablets and Klor
4 Con M10 and M20 microdispersible tablets.

5 Q. And the Klor Con M10 and M20 are recent
6 introductions at Upsher-Smith?

7 A. Yes.

8 Q. As a part of your job, do you remain abreast of
9 the medical literature regarding potassium products and
10 their uses?

11 A. Yes.

12 MR. CROWE: Your Honor, I've provided to
13 complaint counsel, to Your Honor and to Ms. Freese and
14 everyone -- and other counsel copies of exhibits that I
15 will be using with Ms. Freese.

16 JUDGE CHAPPELL: Okay, thank you.

17 BY MR. CROWE:

18 Q. Ms. Freese, could you please turn to the first
19 tab of your exhibit binder.

20 A. Yes.

21 Q. And just to make sure, the document you have is
22 USX 410?

23 A. Yes.

24 Q. Do you recognize this exhibit?

25 A. Yes.

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1 Q. What is it?

2 A. It is the training manual for our Klor Con
3 product line.

4 Q. Did your group help to prepare this training
5 manual?

6 A. Yes, we prepared the technical training portion
7 of this manual.

8 Q. And is this training manual representative of
9 Upsher-Smith's training manual in the 1990s?

10 A. Yes, every year we would look at all of our
11 manuals and make updates if needed, but this is
12 essentially the same manual that we have used for a
13 number of years.

14 Q. Very well.

15 Ms. Freese, could you please turn to -- excuse
16 me.

17 Your Honor, I believe that this exhibit has
18 already been entered into evidence, USX 410, I think it
19 was introduced into evidence yesterday with Mr.
20 Dritsas. If it has not, then I'll come back and I'll
21 move to introduce it into evidence.

22 JUDGE CHAPPELL: Okay, just let me know.

23 BY MR. CROWE:

24 Q. Ms. Freese, could you please turn to Bates page
25 number 190291.

1 A. Okay.

2 Q. Do you recognize this page?

3 A. Yes.

4 Q. Did your group help to prepare this?

5 A. Yes, we would have written or we did write this
6 page in the manual.

7 Q. And I'd like to direct your attention to the
8 second to the last paragraph on page 190291, and I'm
9 going to ask you a few questions about a sentence
10 there, and let me just read it into the record.

11 "It is important to note that liquids,
12 effervescent tablets, and sustained-release tablets are
13 all equally effective in replacing potassium and
14 minimizing side effects."

15 Do you see that sentence, Ms. Freese?

16 A. Yes.

17 Q. And your group helped to draft that language in
18 this training manual?

19 A. Yes, we wrote that.

20 Q. Do you and the people in your group instruct
21 the Upsher-Smith employees about this page and this
22 language as well?

23 A. Yes, this is a -- this is part of our technical
24 training program for all of our representatives.

25 Q. Could you explain what this sentence means?

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1 A. Basically this sentence means that any
2 potassium product could fulfill the potassium
3 requirement that a physician would have. So, if a
4 physician prescribes a specific dose of potassium, any
5 one of the available products would be effective.

6 Q. Could you turn to the next page in this
7 exhibit.

8 A. Yes.

9 Q. So, we are now on Bates page number 190292.

10 A. Yes.

11 Q. Do you recognize this page?

12 A. Yes.

13 Q. Did you or your group prepare this page?

14 A. Yes.

15 Q. And are new Upsher-Smith employees instructed
16 about the contents of this page as well?

17 A. Yes.

18 Q. What is it?

19 A. This is a list of competitive products in the
20 potassium market.

21 Q. Do you instruct new Upsher-Smith employees
22 about how these different products can be used to
23 satisfy the potassium needs of patients?

24 A. Yes.

25 Q. Let me ask you a question. If you go down

1 toward the bottom of the page, you'll see that there's
2 an entry for, "Potassium microencapsulated sustained
3 release tab (10 & 20 mEq)." Do you see that?

4 A. Yes.

5 Q. And then there's a column for the brand name of
6 the drug, and at the time of this training manual, the
7 brand name drugs were K-Dur 10 and K-Dur 20. Do you
8 see that?

9 A. Yes.

10 Q. And it indicates that it was manufactured by
11 Key Pharmaceuticals?

12 A. Yes.

13 Q. Do you see that?

14 Do you train new Upsher-Smith employees about
15 whether or not a K-Dur tablet, 20 mEq, could be
16 satisfied, for example, with a potassium chloride
17 powder 20 mEq?

18 A. Yes, basically we would train the employees
19 that 20 mEq of potassium chloride could be provided
20 with a powder or an effervescent tablet or a liquid or
21 any of the products, as long as the proper dose is
22 satisfied.

23 Q. And on this page, you also give an example of a
24 potassium effervescent tablet, as well, in 20 mEq,
25 right?

1 A. Yes.

2 Q. And there are two brand names that you've
3 listed, K-Care and Klor-vess, right?

4 A. Yes.

5 Q. And for the potassium chloride powder, you've
6 indicated three different brand names, that's Klor Con,
7 Kayciel and Klor, right?

8 A. Yes.

9 Q. And you train Upsher-Smith employees that if a
10 patient needs 20 mEq potassium, that need could be
11 satisfied by any of these products?

12 A. Correct, any of these products that would
13 provide a dose of 20 mEq of potassium would be
14 appropriate to use.

15 Q. What about the potassium wax matrix 10 mEq
16 product?

17 A. Again, the 10 mEq product would -- two 10 mEq
18 products could provide 20 mEq of potassium if that was
19 what the physician had ordered.

20 MR. CROWE: Your Honor, may I approach the
21 witness?

22 JUDGE CHAPPELL: Yes, you may.

23 BY MR. CROWE:

24 Q. Now, Ms. Freese, I've handed you a couple of
25 pills.

1 A. Yes.

2 Q. The first one I handed you is this one here
3 (indicating). Do you recognize the first pill that I
4 handed you?

5 A. Yes, it is a K-Dur 20 tablet.

6 Q. And you've seen a K-Dur 20 tablet before?

7 A. Yes.

8 Q. Is the tablet scored?

9 A. Yes, it is.

10 Q. And what's the purpose of scoring the tablet?

11 A. To make it easy to break.

12 Q. All right. Could you break that in half for
13 me?

14 A. Okay.

15 Q. All right. I handed you a second pill, too,
16 right?

17 A. Yes.

18 Q. Do you recognize that?

19 A. Yes, I'm sorry, a Klor Con 10 wax matrix
20 tablet.

21 Q. All right. How does the size of the Klor Con
22 10 tablet compare to the K-Dur tablet?

23 A. A Klor Con 10 tablet is roughly the size of
24 half of a K-Dur 20 tablet.

25 Q. So, do you teach new Upsher-Smith employees

1 that rather than taking one K-Dur tablet, a patient
2 could take two of the Klor Con 10 --

3 A. Yes.

4 Q. -- wax matrix tablets?

5 A. Yes, that would provide the same
6 milliequivalent dose of potassium.

7 Q. Does that mean that the potassium products that
8 are listed on this page are interchangeable?

9 A. Yes, any one of these potassium products could
10 fulfill the dose requested by a physician for a
11 patient.

12 Q. Now, in the real world, though, are these
13 products really interchangeable?

14 A. Yes.

15 Q. And how do you know that?

16 A. Practicing as a pharmacist in dispensing
17 medications, you would dispense whatever medication was
18 appropriate for that patient. So, if a physician wrote
19 a prescription for 20 milliequivalents of potassium
20 chloride daily, you would dispense whatever product you
21 felt was appropriate that would satisfy that 20
22 milliequivalent need.

23 Q. And if you had a prescription for 20 mEq of
24 potassium a day, you wouldn't necessarily have to fill
25 it with just the K-Dur product?

1 A. No, you could fill it with a powder or with two
2 10s or with -- again, whatever product was appropriate
3 for that patient or whatever product you had available
4 in stock.

5 Q. And is that actually something that you did as
6 a practicing pharmacist?

7 A. Yes.

8 Q. Ms. Freese, you were in the courtroom yesterday
9 when Mr. Dritsas was testifying?

10 A. Yes.

11 Q. And you were present for the discussion
12 regarding switching costs?

13 A. Yes.

14 Q. And the discussion concerned the notion that
15 there are costs to pharmacists of calling doctors to
16 make a therapeutic interchange between potassium,
17 right?

18 A. Right, that was a discussion.

19 Q. Ms. Freese, in your experience, are pharmacists
20 willing to call doctors' offices to make therapeutic
21 substitutions or to get prescriptions changed?

22 A. That's one of the major responsibilities that a
23 pharmacist has, and so throughout the course of a day,
24 a pharmacist spends -- is continuously calling doctors'
25 offices.

1 Q. And why do they do that?

2 A. Well, a pharmacist I think could call a
3 doctor's office for a number of reasons. You know,
4 pharmacies compete against one another, and so if -- if
5 a patient has a prescription and cost is an issue,
6 again, with potassium in particular, elderly patients
7 are often taking a number of medications, and so the
8 pharmacist would want to provide a service to the
9 patient if they expressed concern about the cost of any
10 of their medications. So, you could contact the
11 physician in order to provide that service for one of
12 your -- one of your patients.

13 Q. And is that especially true for long-term
14 prescriptions?

15 A. Absolutely. They will be on this typically for
16 the rest of their lives. They are typically on their
17 antihypertensive drug for the rest of their life. So,
18 potassium is a long-term prescription and an ongoing
19 cost for the patient.

20 Q. And is it a service that's provided by
21 pharmacists?

22 A. Yes.

23 Q. Now, as a matter of fact, was it unusual as a
24 pharmacist to actually call a doctor?

25 A. No, not at all.

1 Q. Is this a topic that you train your sales and
2 marketing personnel on?

3 A. Yes.

4 Q. Has Upsher-Smith's Klor Con 8 and 10 mEq wax
5 matrix business, in fact, depended for a decade on
6 pharmacists being able to do this?

7 A. Yes, particularly with the 10 mEq tablet,
8 pharmacists have contacted physicians in order to
9 change prescriptions for many, many years.

10 Q. Now, is this a service that customers pay for?

11 A. The customer doesn't pay for the pharmacist
12 making that phone call, no.

13 Q. It's a service that's provided by the
14 pharmacist?

15 A. Correct, it is a service that the pharmacist
16 would provide to their patient, who is really their
17 customer.

18 Q. So, this switching cost that you heard about
19 yesterday is not something that's paid for by the
20 customer at all.

21 A. No.

22 Q. It's just a cost of doing business of a
23 business -- of a pharmacy.

24 MS. BOKAT: Objection, leading.

25 JUDGE CHAPPELL: Sustained.

1 BY MR. CROWE:

2 Q. Ms. Freese, could you please turn to tab 2 of
3 your exhibit binder.

4 A. Yes.

5 Q. Do you recognize this document?

6 A. Yes.

7 Q. Does your document bear USX 329 at the bottom?

8 A. Yes.

9 Q. You've seen this document before?

10 A. Yes, I have.

11 MR. CROWE: Your Honor, I can lay a further
12 foundation, but at this time I would move for the
13 admission of USX 329 into evidence.

14 JUDGE CHAPPELL: Any objection?

15 MS. SHORES: None from Schering, Your Honor.

16 MS. BOKAT: No, Your Honor.

17 JUDGE CHAPPELL: USX 329 is admitted.

18 (USX Exhibit Number 329 was admitted into
19 evidence.)

20 MR. CROWE: Thank you, Your Honor.

21 BY MR. CROWE:

22 Q. Ms. Freese, this document relates to a Niacin
23 Advisory Committee. Do you see that?

24 A. Yes.

25 Q. What is or was the Niacin Advisory Committee?

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1 A. Well, this was a group of physicians that
2 Upsher-Smith assembled. We looked to find a group of
3 physicians that we felt were leaders in their field to
4 bring together and talk to them about niacin in general
5 and specifically about Niacor-SR.

6 Q. And there are a list of names and addresses on
7 this page. What are the names and addresses indicated
8 here?

9 A. These are the names of the physicians that we
10 ultimately selected to be a part of our advisory group.

11 Q. Who selected the members of the advisory group?

12 A. We had a meeting or a team of people at
13 Upsher-Smith, and initially everyone from the team
14 would make some recommendations of physicians that they
15 thought would be appropriate for this group, and then
16 later gradually narrowed this list down to this group
17 that's listed here.

18 Q. Were you a member of the team that was involved
19 in selecting the members of the Niacin Advisory
20 Committee?

21 A. Yes.

22 Q. And how did your group decide which members to
23 select?

24 A. Again, we tried to select members that we felt
25 were very experienced in treating patients with

1 cholesterol or lipid disorders, that had experience in
2 using niacin and were considered leaders in their
3 field.

4 Q. And among the members of the Niacin Advisory
5 Committee was Dr. B. Greg Brown of the University of
6 Washington?

7 A. Yes.

8 Q. Ms. Freese, could you please turn to page
9 number 113067 in this exhibit.

10 A. Okay.

11 Q. All right, this page and the pages that follow
12 appear to provide biographical information on the
13 members of the Niacin Advisory Committee, but I see
14 that there are handwritten notes on these pages. Do
15 you recognize the writing?

16 A. Yes, that's my handwriting.

17 Q. All right, let me direct your attention to what
18 you wrote under Dr. Brown's biographical information.
19 You wrote, "FATS, FATS-II, NIH, low HDL Study."

20 What does that mean?

21 A. Well, FATS is an acronym for a study entitled
22 the Familial Artherosclerosis Treatment Study. That's a
23 study that was published in 1990, and Dr. Brown was the
24 lead author of that investigation. That study
25 evaluated the use of niacin in combination with

1 Colestipol or lovastatin in combination with Colestipol
2 versus usual care, and it was very significant in that
3 it's the first study that demonstrated that aggressive
4 lipid-lowering therapy using a combination of agents
5 can actually halt the progression or slow the
6 progression of the disease.

7 Q. What about the other handwritten notes there?

8 A. Yes, FATS-II is more of an internal acronym
9 that I had used, because the patients were patients
10 that were originally in the FATS study, but Dr. Brown
11 continued to study this group of patients, and the
12 patients in the FATS-II study were on a triple
13 combination using lovastatin, niacin and Colestipol.
14 There were actually two arms of the study using either
15 immediate release niacin or sustained release niacin
16 that was -- that were actually Upsher-Smith's niacin
17 products that we were providing for Dr. Brown.

18 And then the last study, the NIH study or low
19 HDL study refers to the HATS study that has just been
20 published. Dr. Brown was in the process of enrolling
21 patients and completing this study, looking at niacin
22 in combination with simvastatin for patients with heart
23 disease and low HDL, and again, the niacin products
24 that Dr. Brown was using were Upsher-Smith's Slo-Niacin
25 and Niacor.

1 Q. Had you read about each of these studies at the
2 time that you wrote this underneath Dr. Brown's
3 qualifications?

4 A. I had read the FATS study, because it had been
5 published in 1990. Neither of these other two studies,
6 FATS-II or the NIH study, had been published yet, but I
7 was very familiar with them because I was the person at
8 Upsher-Smith working with Dr. Brown to supply the
9 medication for the studies.

10 Q. And Upsher-Smith provided both Slo-Niacin and
11 Niacor for those studies?

12 A. Correct. Actually, an over-the-counter
13 Niacor B-3, but we provided both the immediate release
14 niacin and Slo-Niacin for the studies.

15 Q. If you go below Dr. Davignon's qualifications,
16 you wrote, "pravastatin/SR niacin (Nicolaid) study."

17 What does that mean?

18 A. Dr. Davignon had published a study evaluating
19 the use of pravastatin in conjunction with Nicolaid,
20 which was a dietary supplement sustained release niacin
21 that was available at the time.

22 Q. Could you turn the page, please.

23 A. Okay.

24 Q. And next to Professor Hunninghake's name,
25 you've written "NCEP expert panel."

1 A. Yes.

2 Q. What did that mean?

3 A. Dr. Hunninghake is a member and at the time was
4 a member of the National Cholesterol Education Program
5 expert panel, which is a group of physicians and some
6 other health professionals who are experts in managing
7 patients with cholesterol disorders, and the NCEP or
8 the National Cholesterol Education Program writes
9 guidelines for physicians who manage patients'
10 cholesterol disorders.

11 Q. And could you turn to page 113071, and on this
12 page you wrote an arrow from "Cholesterol and Recurrent
13 Events" to "Pravastatin study," which you wrote in.
14 What does that mean?

15 A. The cholesterol and recurrent events study was
16 a study using pravastatin for patients who had
17 established heart disease and elevated cholesterol
18 levels, and so I was just indicating a note that
19 pravastatin was the drug used in that study.

20 Q. Now, Dr. Brown was a member of the Niacin
21 Advisory Committee?

22 A. Yes.

23 Q. As was Dr. Davignon?

24 A. Yes.

25 Q. Dr. Hunninghake?

1 A. Yes.

2 Q. Dr. Pasternak?

3 A. Yes.

4 Q. Why did Upsher-Smith want these people to be
5 members of the committee?

6 A. Because again, we felt that these individuals
7 were all leaders in their field, and in that regard,
8 they were all very well published with regard to
9 treating lipid disorders in general. Many of them were
10 published with regard to niacin specifically, and so we
11 felt that they would be a great group to get insight
12 from.

13 Q. With respect to what product?

14 A. Niacor-SR.

15 Q. Could you turn to tab 3.

16 A. Okay.

17 Q. All right. Have you seen this document before?

18 A. Yes.

19 Q. Does your document bear USX 333?

20 A. Yes.

21 MR. CROWE: Again, Your Honor, if necessary, I
22 can lay a further foundation, but at this time I would
23 move for the admission of USX 333 into evidence.

24 MS. BOKAT: No objection.

25 MS. SHORES: No objection.

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1 JUDGE CHAPPELL: USX 333 is admitted.

2 MR. CROWE: Thank you, Your Honor.

3 (USX Exhibit Number 333 was admitted into
4 evidence.)

5 BY MR. CROWE:

6 Q. You testified that you had seen this document
7 before. What is this document?

8 A. These are actually my personal notes that I
9 created, because I was giving a presentation at the
10 advisory group, so I created these notes in preparation
11 for my presentation.

12 Q. So, this is something you prepared yourself?

13 A. Yes.

14 Q. Ms. Freese, let me direct your attention to the
15 last sentence of the second paragraph on this page, and
16 I'm going to ask you a few questions about it, so I'll
17 just read this statement into the record.

18 "We are looking for your input and impressions
19 to help determine if we are on the right track -- to
20 determine if our impressions of niacin's role are
21 consistent with the impressions of you and your
22 colleagues."

23 First of all, when you stated "you and your
24 colleagues," who were you referring to?

25 A. The members of the Niacin Advisory Panel.

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1 Q. Could you turn the page -- actually, I'm sorry,
2 let's stay on this page.

3 In this statement, you make a reference to "the
4 right track."

5 What did you mean by that?

6 A. Well, we were looking to -- we were looking for
7 the advisory panel group to let us know if our current
8 perceptions of niacin and how we saw niacin fitting
9 into the marketplace now and with the introduction of
10 Niacor-SR were correct. My presentation was going to
11 go through how Upsher-Smith views niacin and the
12 opportunity that we see for niacin in the marketplace,
13 and we wanted their feedback on that.

14 Q. All right. Did you actually give this
15 presentation to the members of the Niacin Advisory
16 Committee?

17 A. Yes.

18 Q. Could you go down toward the bottom of the
19 page, just beneath Roman numeral IV, Statin slide.

20 A. Okay.

21 Q. You refer in the paragraph below that to "combo
22 therapy."

23 Do you see that?

24 A. Yes.

25 Q. Is combo therapy the same thing as combination

1 therapy?

2 A. Yes.

3 Q. What is combination therapy as you used it in
4 this statement?

5 A. Combination therapy refers to using two
6 lipid-lowering agents in combination. Again, with
7 regard to this particular slide, I was discussing the
8 use of niacin in combination with a statin rather than
9 using a higher dose of an individual statin to achieve
10 better efficacy for LDL lowering.

11 Q. Ms. Freese, how was this relevant to Niacor-SR?

12 A. One of the big strategies or one of the big I
13 guess opportunities that we saw for Niacor-SR was using
14 it in combination with the statins.

15 Q. Very well.

16 Ms. Freese, could you please go to tab 4 in
17 your exhibit binder.

18 A. Okay.

19 Q. Ms. Freese, do you recognize this document?

20 A. Yes.

21 Q. This is the agenda of the Niacin Advisory
22 Committee meeting?

23 A. Yes, it is.

24 Q. And does your document bear USX 311?

25 A. Yes.

1 MR. CROWE: Again, Your Honor, I can lay a
2 further foundation, if necessary, but at this point I
3 would move for the admission into evidence of USX 311.

4 MS. BOKAT: No objection.

5 MS. SHORES: No objection.

6 JUDGE CHAPPELL: USX 311 is admitted.

7 (USX Exhibit Number 311 was admitted into
8 evidence.)

9 BY MR. CROWE:

10 Q. Ms. Freese, on this document, there appear to
11 be some dates just beneath Niacin Advisory Meeting, the
12 title of the document, it says "August 15-16, 1996."

13 What's the significance of those dates?

14 A. Those are the dates of the meeting that we had.

15 Q. The meeting of?

16 A. Of the Niacin Advisory Group.

17 Q. Could you turn to the next page for just a
18 moment.

19 A. Okay.

20 Q. It appears that this is a list of the members
21 of the Niacin Advisory Committee. Do you see that?

22 A. Yes.

23 Q. And are these the individuals that attended the
24 meeting on August 15th through the 16th, 1996?

25 A. Yes, with one exception, actually, Dr. Valery

1 Miller I believe had a last-minute emergency, and so I
2 know that she did not attend the meeting, but all of
3 the other physicians were in attendance.

4 Q. So, Dr. Greg Brown attended?

5 A. Yes, he did.

6 Q. Dr. Davignon?

7 A. Yes.

8 Q. Dr. Drobnes?

9 A. Yes.

10 Q. Dr. Hunninghake?

11 A. Yes.

12 Q. Dr. Kafonek?

13 A. Yes.

14 Q. Dr. Kreisberg?

15 A. Yes.

16 Q. Dr. Pasternak?

17 A. Yes.

18 Q. And Dr. Stein?

19 A. Yes.

20 Q. And Dr. Stein, was he the chairman of the
21 Niacin Advisory Committee?

22 A. Yes, he was.

23 Q. The meeting took place in Minneapolis?

24 A. Yes.

25 Q. Going back to the first page on this tab, it

1 says, "Primary Objective: To develop strategies for
2 promoting Niacor and Niacor-SR to the medical
3 community."

4 Why was this an objective of the meeting?

5 A. The reason we had assembled this group of
6 physicians is that we wanted to get their feedback and
7 their input about how best to launch and position
8 Niacor-SR when we launched.

9 Q. And below that, there's an agenda, and it
10 indicates that Ian Troup was to deliver the
11 introduction and welcoming remarks, as well as Dr.
12 Stein. You were to give a presentation. Drs.
13 Halvorsen and Drobnes were to give presentations, and
14 then Evan Stein was to lead some kind of discussion
15 group.

16 Did all of those people attend the meeting?

17 A. Yes.

18 Q. And does this agenda accurately reflect the
19 order in which each of these individuals gave a
20 presentation to the Niacin Advisory Committee?

21 A. Yes, it does.

22 Q. You gave a presentation about niacin's role at
23 Upsher-Smith and Upsher-Smith's perspective of niacin?

24 A. Yes.

25 Q. This indicates that Mark Halvorsen gave a

1 presentation relating to the efficacy data.

2 A. Correct.

3 Q. Was that the efficacy data of Niacor-SR's
4 clinical trials?

5 A. Yes, it was.

6 Q. And did Dr. Drobnes give a presentation
7 regarding Niacor-SR's safety data?

8 A. Yes, she did.

9 Q. And that would be the safety data from the
10 clinical trials?

11 A. Yes.

12 Q. Did any of the members of the Niacin Advisory
13 Committee indicate that they believed the efficacy or
14 the safety data that was presented to them was
15 unacceptable?

16 A. No, not at all.

17 Q. What was your impression of the -- well, let me
18 ask you this: Did the Niacin Advisory Committee give
19 you any ideas about how to market Niacor-SR?

20 A. Yes, we had actually a very lengthy discussion
21 about marketing Niacor-SR. One of the things I
22 remember talking about quite a bit was the need for a
23 strong educational program to educate physicians about
24 how to use niacin and that really by implementing a
25 program like that that most physicians should be able

1 to safely and effectively use niacin and Niacor-SR
2 specifically.

3 Q. They thought that with enough education, most
4 physicians would prescribe niacin?

5 A. Yes.

6 MS. BOKAT: Objection, hearsay.

7 JUDGE CHAPPELL: Why are you offering this?

8 MR. CROWE: I can restate the question, Your
9 Honor.

10 JUDGE CHAPPELL: Okay.

11 BY MR. CROWE:

12 Q. Did they give you an opinion about how many
13 physicians they thought would prescribe a niacin
14 product?

15 MS. BOKAT: Objection. Well, maybe I should
16 have let him ask whether she did get an opinion. I'll
17 wait for the next one, if I may withdraw that, please.

18 MR. CROWE: All right, I'll lay a foundation.

19 BY MR. CROWE:

20 Q. Did the members of the Niacin Advisory
21 Committee give you an opinion about whether or not they
22 believed that physicians would prescribe Niacor-SR?

23 A. Yes, they believed --

24 Q. And what was that opinion?

25 A. I'm sorry.

1 MS. BOKAT: Now I raise my objection that it's
2 hearsay.

3 MR. CROWE: Your Honor, I'm not offering this
4 statement for the truth of the matter asserted. It
5 goes to Upsher-Smith's perceptions of the marketability
6 of Niacor-SR, goes to Upsher-Smith's state of mind.

7 MS. SHORES: Your Honor, it seems to me it also
8 goes to the state of mind of the declarants in this
9 case, the members of the advisory committee.

10 JUDGE CHAPPELL: Ms. Bokat, if he's not
11 offering it for the truth, then it's not hearsay, so
12 it's overruled.

13 BY MR. CROWE:

14 Q. You can answer the question.

15 A. Could you repeat the question?

16 The -- the niacin -- we had a discussion
17 regarding Niacor-SR, and we had a discussion with
18 regard to the importance of an educational component in
19 marketing Niacor-SR, and when we discussed that, the
20 physicians indicated that they felt most physicians
21 would be able to effectively prescribe and would use
22 Niacor-SR.

23 Q. Thank you.

24 Ms. Freese, could you please turn to tab 5 of
25 this exhibit binder. Before I get to Exhibit 5,

1 though, let me ask -- let me just conclude our
2 discussion of the Niacin Advisory Committee meeting.

3 What did -- how did you -- what was your
4 reaction overall to the meeting with these physicians?

5 A. I thought it was a very good meeting, and I and
6 I think others from Upsher-Smith left the meeting
7 excited about the prospects for Niacor-SR.

8 Q. All right. Now, let's turn to tab 5. Ms.
9 Freese, do you recognize this document?

10 A. Yes.

11 Q. Have you seen this before?

12 A. Yes.

13 Q. Does your document bear USX 539?

14 A. Yes.

15 MR. CROWE: Your Honor, I can lay a further
16 foundation, but at this point I would move for the
17 admission into evidence of USX 539.

18 MS. BOKAT: No objection.

19 MS. SHORES: No objection, Your Honor.

20 JUDGE CHAPPELL: USX 539 is admitted.

21 MR. CROWE: Thank you, Your Honor.

22 (USX Exhibit Number 539 was admitted into
23 evidence.)

24 BY MR. CROWE:

25 Q. Ms. Freese, this document appears to be a

1 meeting agenda for May 28, 1997 for Searle or relating
2 to Searle International.

3 First of all, did you attend a meeting on
4 behalf of Upsher-Smith, a meeting with Searle
5 International?

6 A. Yes.

7 Q. And what was the date of the meeting?

8 A. The meeting occurred on May 28th, 1997.

9 Q. Where did the meeting take place?

10 A. At Searle, which I believe was in Chicago.

11 Q. Who attended on behalf of Upsher-Smith?

12 A. I attended, Vickie O'Neill attended the
13 meeting, Mark Halvorsen, Dr. Claude Drobnes and Dr.
14 Greg Brown attended on behalf of Upsher-Smith.

15 Q. What is Searle International?

16 A. They are a pharmaceutical company.

17 Q. What was the purpose of the meeting?

18 A. We were meeting with Searle to discuss the
19 potential out-licensing of Niacor-SR outside of the
20 U.S., in Europe specifically.

21 Q. Was only non-U.S. licensing discussed at the
22 meeting?

23 A. Yes, we discussed only licensing the product
24 outside of the U.S.

25 Q. Why wasn't licensing Niacor-SR in the U.S.

1 discussed?

2 A. Because Upsher-Smith had always planned to and
3 was planning on license -- excuse me, was planning on
4 marketing Niacor-SR, introducing it and marketing it in
5 the U.S. ourselves.

6 Q. Why is that?

7 A. Because we saw great potential for Niacor-SR in
8 the U.S. we don't have representatives outside of the
9 U.S., and so to capture or to take advantage of the
10 potential we thought it had outside of the U.S., we
11 were looking at an out-licensing opportunity, but in
12 terms of within the United States, that was something
13 that Upsher-Smith wanted to do.

14 Q. Did you have an -- did people at Upsher-Smith
15 have an opinion about the potential sales of Niacor-SR
16 in the United States?

17 A. Yes. In discussions with people at
18 Upsher-Smith, I think most people thought that
19 Niacor-SR had the potential to be a \$50 to \$100 million
20 product. I know occasionally I heard figures higher
21 than that, but I think everybody at Upsher-Smith agreed
22 that it was going to be a successful product for us.

23 Q. Ms. Freese, this meeting with Searle
24 International dealt only with Niacor-SR?

25 A. Yes.

1 Q. Now, I see that Dr. Brown attended the meeting
2 on behalf of Upsher-Smith as well?

3 A. Yes, he did.

4 Q. And you testified that he was there?

5 A. Yes.

6 Q. Dr. Brown wasn't involved in any of the
7 clinical studies relating to Niacor-SR, was he?

8 A. Not to my knowledge, no.

9 Q. Why did you invite Dr. Brown to give a
10 presentation relating to Niacor-SR?

11 A. Well, Dr. Brown was, again, an opinion leader
12 in his field, and Dr. Brown uses niacin extensively.
13 In fact, he has used Upsher-Smith's niacin products
14 extensively for the NIH low HDL study. We were
15 supplying him with Slo-Niacin, and Slo-Niacin is
16 virtually the same -- the same product as Niacor-SR.
17 They are a different color, but they're virtually the
18 same product. And so he had a lot of experience with
19 Slo-Niacin, and that seemed to make sense and be
20 relevant to Niacor-SR.

21 Q. Did he have a positive experience with
22 Slo-Niacin?

23 A. Yes.

24 Q. Ms. Freese, you've testified about who was
25 there on behalf of Upsher-Smith. Do you remember who

1 was there from Searle?

2 A. I don't remember the names of the individuals,
3 no.

4 Q. Do you remember how many people were present at
5 the meeting from Searle?

6 A. You know, I think that there were probably two
7 or three, but I'm not sure.

8 Q. Now, if we turn back to the document for a
9 moment, this seems to indicate that you gave a
10 presentation relating to the treatment strategies for
11 hypercholesterolemia. Is that right?

12 A. Yes.

13 Q. And were presentations given to Searle
14 International relating to the safety and efficacy of
15 Niacor-SR?

16 A. Yes.

17 Q. Did Dr. Halvorsen discuss the efficacy of
18 Niacor-SR?

19 A. Yes, he did.

20 Q. And did Dr. Drobnes discuss the safety of
21 Niacor-SR?

22 A. Yes.

23 Q. Was this information based upon the clinical
24 studies?

25 A. Yes, it was.

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1 Q. Did the representatives of Searle ask questions
2 during the discussion?

3 A. Yes. I know that throughout my presentation
4 and throughout really the entire meeting, we had a
5 discussion.

6 Q. And how did you leave the meeting with Searle
7 International?

8 A. Well, the meeting was left with a discussion of
9 what some of the next steps were. My understanding was
10 that Searle was going to further evaluate the
11 information that we had presented and that they would
12 be getting back to Upsher-Smith.

13 Q. Were you optimistic?

14 A. Yes.

15 Q. Why?

16 A. I think that the discussion went well. They
17 seemed interested in the discussion and asked a lot of
18 questions, and again, when we left the meeting, I
19 thought that they were going to or they had indicated
20 that they were going to review the information and get
21 back to us.

22 Q. All right. Ms. Freese, now this meeting with
23 Searle International took place May 28th, 1997,
24 correct?

25 A. Yes, it did.

1 Q. All right. Could you turn to tab 6 in your
2 exhibit binder. Ms. Freese, I'll ask you if you
3 recognize this document.

4 A. Yes.

5 Q. What is it?

6 A. This -- the cover page is a memo, and it's
7 attached to a draft package insert for Niacor-SR.

8 Q. You are copied on this memo?

9 A. Yes.

10 Q. Did you draft the package insert?

11 A. Yes, I did.

12 Q. Does your document bear USX 308?

13 A. Yes.

14 MR. CROWE: Your Honor, at this time I'd move
15 for the admission into evidence of USX 308.

16 MS. BOKAT: No objection.

17 MS. SHORES: No objection.

18 JUDGE CHAPPELL: That's 308?

19 MR. CROWE: I'm sorry?

20 JUDGE CHAPPELL: What was the number?

21 MR. CROWE: USX 308.

22 JUDGE CHAPPELL: USX 308 is admitted.

23 (USX Exhibit Number 308 was admitted into
24 evidence.)

25 BY MR. CROWE:

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1 Q. Ms. Freese, could you turn to the second page
2 of this exhibit.

3 A. Okay.

4 Q. Is this the beginning of the draft package
5 insert that you prepared?

6 A. Yes.

7 Q. Did you prepare the whole draft package insert?

8 A. We prepared it as a group, but I actually
9 drafted much of it, and then we would have group
10 discussion around sections that I drafted.

11 Q. Ms. Freese, could you please turn to USX page
12 110468.

13 A. Okay.

14 Q. And I'd like to draw your attention to the
15 bottom half of this page. There's a reference there to
16 the National Cholesterol Education Program or NCEP
17 treatment guidelines, and then it provides a table.

18 A. Yes.

19 Q. Did you draft this portion of the package
20 insert?

21 A. Yes.

22 Q. And if we turn the page, the description of the
23 NCEP guidelines continues. Is that right?

24 A. Yes.

25 Q. And I see that there's a column there for

1 annotations. What's the significance of the annotation
2 "NCEP, Circ 1994; 89(3); 1329-1445(1)"?

3 A. That is the specific publication where the NCEP
4 guidelines were published. They were published in the
5 medical journal Circulation for 1994. The "1" I
6 believe just referred to it was the first reference
7 that we used in the package insert.

8 Q. And was this the basis for the information
9 contained in Table IV and the description of the NCEP
10 guidelines?

11 A. Yes.

12 Q. Could you please turn to page 110474.

13 A. Okay.

14 Q. And I'd like to draw your attention again to
15 the bottom half of the page, Dosage and Administration.
16 Do you see that?

17 A. Yes.

18 Q. Did you prepare the portion of the draft
19 package insert related to the dosage and
20 administration?

21 A. Yes, I did.

22 Q. All right, let me -- I am going to ask you a
23 few questions about the following paragraph, and so I
24 just want to read it into the record so we have a
25 context.

1 "The usual adult dose of Niacor-SR is 1000 mg
2 to 1500 mg daily, to be taken in divided doses (i.e.
3 twice daily). The maximum recommended dose is 2000 mg
4 daily, to be taken in divided doses. The dose of
5 Niacor-SR should be individualized according to the
6 patient's response. Niacor-SR should be taken with
7 meals."

8 Did I read that correctly?

9 A. Yes.

10 Q. Did you draft this portion of the draft package
11 insert?

12 A. Yes.

13 Q. What was the basis for the information that you
14 set forth in this part of the draft package insert?

15 A. It was based on the Niacor-SR clinical program
16 and how patients were dosed in the clinical program, as
17 well as the -- you know, the need for niacin dosing to
18 be individualized is really, again, based on just, you
19 know, general niacin literature.

20 Q. Medical literature?

21 A. Correct, medical literature. Reviewing niacin
22 would indicate that each patient needs to be dosed
23 according to their own response.

24 Q. All right. Let me turn to the next paragraph
25 there.

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1 "Flushing of the skin may occur, especially
2 during dose escalation, and may be minimized by
3 pre-treatment with aspirin approximately 30 minutes
4 prior to administration of Niacor-SR. Tolerance to the
5 flushing reaction will generally develop rapidly over
6 the course of several weeks of continued treatment.
7 Flushing, pruritus and gastrointestinal distress may be
8 reduced by avoiding administration with alcohol or hot
9 liquids and by taking Niacor-SR with meals."

10 Did you draft this portion of the draft package
11 insert?

12 A. Yes, I did.

13 Q. And what was the basis for the information that
14 you wrote with respect to the flushing?

15 A. The references listed to the right both
16 specifically address flushing and discuss the use of
17 aspirin to reduce flushing and then also go into detail
18 about how patients -- or the flushing reaction will
19 generally -- will generally subside over time or
20 patients will develop a tolerance to that flushing
21 reaction over time. So, there are three references
22 there, and they all discuss that in detail.

23 Q. Could you turn the page, please.

24 A. Okay.

25 Q. You're on page 110475?

1 A. Yes.

2 Q. At the top of this page, it says, "Dosing
3 considerations related to gender and BMI information."

4 Did you write that?

5 A. Yes.

6 Q. First of all, let me ask you, what is BMI?

7 A. Body mass index.

8 Q. Can you explain this statement contained in the
9 draft package insert?

10 A. This is a notation to add more information, so
11 we didn't have all of the information available at this
12 time, but we were in the process of evaluating if it
13 would make sense to or be important to have to have
14 different dosing recommendations based on somebody's
15 gender or on their weight.

16 Q. Now, let me turn your attention to Dose
17 Titration.

18 A. Okay.

19 Q. Did you write the portion of the draft package
20 insert relating to dose titration?

21 A. Yes.

22 Q. There's a statement in here that I just want to
23 ask you a couple of questions about. It says:

24 "Evaluate the patient's lipoprotein response.
25 Base the decision to adjust the dose on the patient's

1 response to therapy and established treatment
2 guidelines."

3 Did you write that?

4 A. Yes.

5 Q. What's the basis for the information that you
6 provided with respect to dose titration?

7 A. Well, the dose titration portion is, again,
8 based on the clinical studies for Niacor-SR, and then
9 evaluating the patient's lipoprotein response is based
10 on the significant literature with niacin. The dose
11 titration brings the patient to a total daily dose of
12 1000 milligrams, and for increasing the dose, it would
13 be important to evaluate the efficacy, because if a
14 patient were meeting their treatment guidelines, you
15 wouldn't need to increase the dose any further.

16 Q. And why is escalating the dosage important --
17 I'm sorry, why is titration important?

18 A. It's important to titrate niacin just to
19 improve its tolerability.

20 Q. Now, could you turn to the bottom of the page.
21 You wrote a paragraph there -- I'm sorry, did you write
22 this paragraph?

23 A. I did write it.

24 Q. All right. And it's about concomitant therapy?

25 A. Yes.

1 Q. Is concomitant therapy the same thing as
2 combination therapy?

3 A. Yes, it is.

4 Q. All right, let me read this paragraph into the
5 record just so I can ask you some questions based on
6 it.

7 "Greater lipid-lowering effects have been
8 reported when either immediate-release or
9 extended-release niacin have been used in combination
10 with a bile acid sequestrant or an HMG-CoA reductase
11 inhibitor."

12 That's what you wrote in the draft package
13 insert?

14 A. Yes, it is.

15 Q. What is HMG-CoA?

16 A. That's another term for the statin drugs.

17 Q. And what was the relevance of the concomitant
18 therapy to Niacor-SR?

19 A. Well, the references to the right all provide
20 basis for the fact that niacin is used extensively and
21 in combination. There's a number of publications
22 looking at niacin in combination with both the bile
23 acid sequestrants and the HMG-CoA reductase inhibitors
24 or the statins. Upsher-Smith saw a good opportunity
25 for Niacor-SR to be used in combination with these

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1 drugs.

2 Q. All right, one last question. Could you please
3 turn back to the first page of this tab.

4 A. Yes.

5 Q. The date of this memo to which the draft
6 package insert was attached was July 21st, 1997?

7 A. Yes.

8 Q. What did you think about Niacor-SR on July
9 21st, 1997?

10 A. Well, we were still actively working to
11 complete the Niacor-SR package insert, because we
12 needed to have that as part of the NDA submission for
13 Niacor-SR.

14 Q. And did you think that Niacor-SR was still
15 going to be a successful drug?

16 A. Yes.

17 MR. CROWE: Thank you, Ms. Freese.

18 Thank you, Your Honor, no further questions.

19 JUDGE CHAPPELL: Does Schering have any direct
20 for this witness?

21 MS. SHORES: No, Your Honor.

22 JUDGE CHAPPELL: Cross?

23 MS. BOKAT: Yes, please.

24 JUDGE CHAPPELL: You may proceed.

25 MS. BOKAT: Thank you.

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1 CROSS EXAMINATION

2 BY MS. BOKAT:

3 Q. Good morning, Ms. Freese.

4 A. Good morning.

5 Q. You were just talking about the work you did on
6 the preparation of the package insert for Niacor-SR.
7 Do you recall when you began that work?

8 A. I'm not sure when I began it, no.

9 Q. Do you know what year?

10 A. I would imagine that I began it toward the
11 beginning of 1997 or perhaps the end of the year before
12 that.

13 Q. Before the 17th of June, 1997, did you
14 personally have any meetings with Schering-Plough about
15 Niacor-SR?

16 A. No.

17 Q. Before June 17th, 1997, did you have any
18 communications with anyone at Schering-Plough about
19 Niacor-SR?

20 A. No.

21 Q. After June 1997, did you have any meetings with
22 anyone at Schering-Plough about Niacor-SR?

23 A. No.

24 Q. After June 17th, 1997, did you have any
25 communications with anyone at Schering-Plough about

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1 Niacor-SR?

2 A. No.

3 Q. Did Schering ever ask for information about the
4 package insert you were preparing for Niacor-SR?

5 A. I never communicated with Schering about
6 Niacor-SR.

7 Q. So, you're not aware of them asking about the
8 package insert for Niacor-SR.

9 A. They did not ask me personally about it, no.

10 Q. Did you get any inquiry indirectly from someone
11 else?

12 A. Well, the package insert was something we
13 created as a team, and so it was something that was
14 available as part of a project team for Niacor-SR, but
15 nobody specifically called me and asked me to give them
16 a copy of it outside of the Niacor-SR project team
17 meetings.

18 Q. So, you didn't give any information to anyone
19 at Schering-Plough about the package insert on
20 Niacor-SR.

21 A. I did not directly communicate with
22 Schering-Plough about the Niacor-SR package insert.

23 Q. Did you communicate indirectly?

24 A. Again, I provided it for the project team, and
25 so they all had access to the information. So, I --

1 no, I did not specifically provide it for
2 Schering-Plough. I don't know if it was provided to
3 Schering-Plough from somebody else on the project team.

4 Q. You were speaking earlier with Mr. Crowe about
5 a meeting between Upsher-Smith and Searle.

6 A. Yes.

7 Q. And you said you didn't remember the names of
8 any of the Searle people who were at that meeting.

9 A. That's correct.

10 Q. Do you remember what their positions were?

11 A. I really don't remember the individuals from
12 Searle who attended the meeting.

13 Q. Do you recall whether there were any scientists
14 from Searle at that meeting?

15 A. Again, I just don't remember the specific
16 titles or names of the individuals from Searle that
17 attended.

18 Q. Do you recall whether there were any marketing
19 people from Searle at that meeting?

20 A. I don't recall the titles of the people from
21 Searle, so I don't know what areas exactly they were
22 representing.

23 Q. But there were multiple people from Searle in
24 attendance. Is that right?

25 A. There was -- there was definitely more than

1 one. There were I think two or three people.

2 Q. At the meeting with Searle, you personally made
3 a presentation about hypercholesterolemia treatment,
4 right?

5 A. Yes.

6 Q. Did Mr. Halvorsen make a presentation about the
7 efficacy of Niacor-SR?

8 A. Yes.

9 Q. Did Dr. Drobnes make a presentation about the
10 safety of Niacor-SR?

11 A. Yes.

12 Q. Did Ms. O'Neill make a presentation at the
13 meeting with Searle?

14 A. Yes, she introduced the meeting or initiated
15 the meeting and then provided some background on I
16 believe the description of Niacor-SR and patent
17 information.

18 Q. Do you recall what patents she discussed at the
19 meeting?

20 A. I don't recall the patent numbers. I believe
21 one of the patents is called the O'Neill patent. I
22 think she discussed two patents.

23 Q. Do you recall the other patent that she
24 discussed at the Searle meeting?

25 A. You know, I'm not sure what the name of that

1 patent is.

2 Q. Do you have any recollection of that other
3 patent?

4 A. I believe she discussed two patents, and again,
5 I recall the one was called the O'Neill patent. The
6 other perhaps was called the Evenstad patent, but
7 again, I'm not sure.

8 Q. Do you recall what those patents cover or
9 claim?

10 A. They are both related to Niacor-SR.

11 Q. Do you know what features of Niacor-SR they
12 cover?

13 A. One patent covers dosing and one patent covers
14 I believe formulation, but I really don't know the
15 details of either of the patents.

16 Q. Did Ms. O'Neill present information about the
17 coverage of those patents at the meeting with Searle?

18 A. You know, I believe she gave relatively brief
19 introductory remarks, and I don't know that she got
20 into a lot of detail. She covered the two patents. I
21 really don't remember the details of what she
22 presented.

23 Q. After the meeting, Searle was going to analyze
24 the Niacor-SR product further, were they not?

25 A. Yes, they were going to review the information

1 that we had presented.

2 Q. At the end of the meeting with Searle, you were
3 not able to assess Searle's level of interest in
4 Niacor-SR, were you?

5 A. Well, we had discussion throughout the meeting,
6 and they asked a lot of questions, and they certainly
7 appeared interested to me.

8 MS. BOKAT: Your Honor, may I approach the
9 witness, please?

10 JUDGE CHAPPELL: Yes.

11 MS. BOKAT: And I'm going to need some help
12 from Ms. Hertzman with the ELMO here.

13 BY MS. BOKAT:

14 Q. Ms. O'Neill, do you recall being deposed by one
15 of my colleagues in October of 2001?

16 A. I'm Lori Freese.

17 Q. I'm sorry, what did I --

18 A. Ms. O'Neill you called me.

19 Q. I'm sorry, Ms. Freese.

20 Do you recall being deposed by one of my
21 colleagues in October?

22 A. Yes.

23 Q. During that deposition, were you not asked and
24 did you not answer --

25 MS. SHORES: Objection. Could you give us a

1 page reference?

2 MS. BOKAT: Page 25, beginning at line 4.

3 BY MS. BOKAT:

4 Q. "QUESTION: Were you able to assess Searle's
5 level of interest in Niacor-SR at the May 1997 meeting
6 between Upsher-Smith and Searle?

7 "ANSWER: I don't know what their level of
8 interest was. I don't remember."

9 A. Yes.

10 Q. That was your testimony, correct?

11 A. Correct. Again, I think I discussed that we
12 had a discussion throughout the presentation. I don't
13 know exactly what they were thinking, but we certainly
14 had a discussion as we were talking about all of the
15 presentations.

16 Q. But you didn't know what their level of
17 interest was, did you?

18 A. No, I didn't know specifically what they were
19 thinking, no.

20 Q. I believe you mentioned that you had occasion
21 to call on some of Upsher-Smith's accounts.

22 A. Yes.

23 Q. Did anyone else accompany you on those calls?

24 A. Yes, traditionally if I were to call on an
25 account, I would accompany one of our sales

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1 representatives.

2 Q. What kinds of accounts were you calling on?

3 A. Usually when I accompany a representative, it
4 would be to talk with a physician, but I would
5 occasionally go on a call to a managed care
6 organization or other health professionals.

7 Q. Are your offices in Minnesota?

8 A. Yes.

9 Q. The sales reps that went with you when you were
10 calling on physicians and managed care organizations,
11 where are those sales representatives located?

12 A. Well, we have sales representatives who are
13 also located in Minnesota, but we do have sales
14 representatives who are located across -- you know, in
15 other states as well.

16 Q. When you made the calls on physicians and
17 managed care organizations, did sales representatives
18 from your offices in Minnesota accompany you?

19 A. On some of the calls, and on some of the calls
20 I may have met one of our representatives that works
21 outside of Minnesota.

22 Q. Where were the physicians located upon whom you
23 called?

24 A. They were located in various states.

25 Q. But many of them were outside of Minnesota?

1 A. Yes.

2 Q. Were many of the managed care accounts upon
3 whom you called also located outside of Minnesota?

4 A. Yes, many were located inside Minnesota, but I
5 would travel outside of Minnesota as well.

6 Q. Ms. Freese, do you still have the white binder
7 that Mr. Crowe gave you? Is that right?

8 A. Yes.

9 Q. I'm going to ask you if you would turn to tab
10 number 1, please.

11 A. Okay.

12 Q. Specifically at a page that in the lower
13 right-hand corner bears the number 190291.

14 A. Okay.

15 Q. This is a page within Upsher-Smith's training
16 manual, right?

17 A. Yes, it is.

18 Q. As to potassium chloride supplements in liquid
19 form, patients have complained about carrying bottles
20 of potassium chloride around because of the
21 inconvenience, correct?

22 A. Correct, for many patients the liquid form
23 isn't the most convenient. It would really depend on
24 the patient and where they were located, their setting.

25 Q. But some patients complain about the

1 inconvenience of the liquids, correct?

2 A. Yes.

3 Q. Has taste been a problem with the effervescent
4 potassium chloride supplements?

5 A. The effervescent tablets were designed to
6 overcome taste issues that were apparent with the
7 liquid product, but certainly taste can be an issue
8 with potassium.

9 Q. If you look in the middle of that page, there's
10 a paragraph that begins with the word "Powders."

11 A. Yes.

12 Q. The second sentence in that paragraph reads,
13 "Taste continued to be a problem and effervescent
14 tablets for reconstitution were created in an effort to
15 mask the taste."

16 So, the taste problem was with the powders?

17 A. Correct, and then effervescent tablets are
18 designed to help improve the tolerability -- not
19 tolerability, but to improve the taste, make them taste
20 better and improve the acceptance.

21 Q. So, for patients, there was a taste problem
22 with the potassium chloride in powder form, right?

23 A. Again, not with all patients, but certainly the
24 effervescent form was designed to taste better than the
25 powder form.

1 Q. You mentioned that at one time you were a
2 licensed pharmacist in Minnesota.

3 A. I am still a licensed pharmacist in Minnesota.

4 Q. As a licensed pharmacist, if you were given a
5 prescription written for K-Dur 20 tablets, you couldn't
6 substitute a tablet in an 8 or 10 dosage strength
7 without calling the physician, could you?

8 A. Correct, if it was written specifically for
9 K-Dur 20 mEq tablet, I would contact the physician
10 before I would substitute another product.

11 Q. Because without contacting the physician, you
12 were not permitted to make that substitution, correct?

13 A. Correct.

14 Q. If you as a pharmacist receive a prescription
15 written for K-Dur 20, you're not allowed to substitute
16 a powder or a liquid or an effervescent tablet without
17 contacting this physician, can you?

18 A. Not if it were specifically written for K-Dur
19 20.

20 Q. But if you got a prescription, again, for
21 K-Dur -- written for K-Dur 20, you could substitute the
22 Klor Con M20 tablet, correct?

23 A. Yes.

24 Q. You mentioned earlier this morning that
25 patients don't pay the cost of the pharmacist

1 contacting the physician for authorization to
2 substitute a potassium chloride product, but there are
3 costs in that transaction, are there not?

4 A. Well, pharmacists are on the phone with
5 physicians all the time. It's really a part of their
6 daily practice, and so I don't know that you could, you
7 know, put a cost to one phone call. Pharmacists make
8 hundreds of phone calls to physicians' offices every
9 day.

10 Q. But each of those calls takes a certain amount
11 of pharmacist time.

12 A. Yes.

13 Q. And that time has a cost associated with it.

14 A. Not a cost to the patient. It's just part of
15 the practice of being a pharmacist.

16 Q. But there's a cost to the pharmacy.

17 A. Yes, there is a cost to the pharmacy, you know,
18 not -- the pharmacist is a cost to the pharmacy, but I
19 don't know that you can look at one phone call or --
20 you know, it takes time for the pharmacist to count the
21 pills and put them in the bottle. I don't know that
22 you can break down each action that the pharmacist
23 makes as an individual cost. So, overall, you know,
24 the pharmacist is, again, on the phone all the time
25 with physicians.

1 Q. But when the pharmacist gets the prescription
2 written for K-Dur 20, he or she can substitute the Klor
3 Con M20 without the attendant cost of contacting the
4 physician, right?

5 A. The pharmacist would not have to call a
6 physician to substitute the M20 for the K-Dur 20.

7 Q. You talked with Mr. Crowe this morning about
8 the meeting of Upsher's Niacin Advisory Committee.

9 A. Yes.

10 Q. Did Schering inquire about that advisory
11 committee meeting?

12 A. I don't know.

13 Q. But they never inquired of you.

14 A. No, they never contacted me.

15 Q. And you're not aware of Schering having
16 contacted anyone about the Niacin Advisory Committee
17 meeting.

18 A. I don't know if they contacted someone else or
19 not.

20 MS. BOKAT: Could I have just a second, Your
21 Honor, to find something on this page?

22 JUDGE CHAPPELL: Yes.

23 MS. BOKAT: Thank you.

24 (Brief pause.)

25 BY MS. BOKAT:

1 Q. Ms. Freese, would you be willing to turn to tab
2 6 in your notebook, please.

3 A. Okay.

4 Q. This is the draft package insert for Niacor-SR,
5 correct?

6 A. Yes, it is.

7 Q. And with Ms. Hertzman's help, we are looking at
8 a page numbered 110474.

9 A. Okay.

10 Q. After the heading Dosage and Administration on
11 that page, in the second paragraph, the last sentence
12 reads, "Niacor-SR should be taken with meals."

13 So, Niacor-SR wasn't approved for nighttime
14 dosing, right?

15 A. Correct.

16 Q. You mentioned that Niacor-SR and Upsher's
17 Slo-Niacin are virtually the same product.

18 A. Correct, the formulation is basically the same
19 with the exception of some inactive ingredients; the
20 color, for instance. But it's basically the same
21 formulation.

22 Q. Did Upsher-Smith try to license Slo-Niacin?

23 A. To?

24 Q. Out-license to anyone to market that product.

25 A. I don't know.

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1 Q. Not that you're aware of?

2 A. Not that I'm aware of.

3 MS. BOKAT: Thank you very much, Your Honor.

4 That concludes my cross examination.

5 JUDGE CHAPPELL: Redirect?

6 MR. CROWE: Yes, Your Honor.

7 REDIRECT EXAMINATION

8 BY MR. CROWE:

9 Q. Ms. Freese, if you got a prescription for K-Dur
10 10, you couldn't substitute that with Klor Con 10 wax
11 matrix without calling a physician first, right?

12 A. Correct.

13 Q. And yet Klor Con 10 wax matrix tablets were
14 sold because physicians would do -- or pharmacists
15 would do just that.

16 A. Correct, you could contact a physician and then
17 substitute a 10 mEq tablet.

18 Q. Ms. Freese, were you the person at Upsher-Smith
19 responsible for communicating with Schering?

20 A. No.

21 Q. You wouldn't know the details of any
22 communications between Schering-Plough and Ian Troup?

23 A. No.

24 Q. Or Mark Halvorsen?

25 A. No.

1 Q. Or Marge Garske?

2 A. No.

3 Q. Or Paul Kralovec?

4 A. No.

5 MR. CROWE: Thank you, Ms. Freese.

6 No further questions, Your Honor.

7 MS. BOKAT: Nothing further from complaint
8 counsel, Your Honor.

9 JUDGE CHAPPELL: Thank you, Ms. Freese. You're
10 excused.

11 THE WITNESS: Thank you.

12 MR. CURRAN: Your Honor, Upsher-Smith now calls
13 Paul Kralovec.

14 JUDGE CHAPPELL: Raise your right hand, please.
15 Whereupon--

16 PAUL D. KRALOVEC
17 a witness, called for examination, having been first
18 duly sworn, was examined and testified as follows:

19 JUDGE CHAPPELL: Thank you, have a seat.

20 State your full name for the record, please.

21 THE WITNESS: My name is Paul Douglas Kralovec.

22 JUDGE CHAPPELL: Thank you.

23 MR. CURRAN: Your Honor, at some point during
24 this examination, I intend to refer to documents. May
25 I circulate the binders?

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1 JUDGE CHAPPELL: Yes, please. Let's try to
2 break sometime around or after 11:15.

3 MR. CURRAN: Very good, Your Honor.

4 DIRECT EXAMINATION

5 BY MR. CURRAN:

6 Q. Mr. Kralovec, can you please describe generally
7 your educational background?

8 A. Yes, I have a Bachelor's of Science in
9 accounting, and I have an MBA from the University of
10 Minnesota.

11 Q. Sir, are you a CPA?

12 A. I am.

13 Q. Have you worked as a CPA?

14 A. I did. I worked for a little more than a year
15 at a company called Deloitte, Haskins & Sells, now
16 called Deloitte & Touche.

17 Q. Sir, do you have any special pharmaceutical or
18 medical education?

19 A. No.

20 Q. Sir, today, you are the chief financial officer
21 of Upsher-Smith, correct?

22 A. That's correct.

23 Q. Okay. I'd like to review briefly the course of
24 your employment at Upsher-Smith. Sir, when did you
25 join Upsher-Smith?

1 A. I joined Upsher-Smith in November of 1984.

2 Q. Okay. In what position?

3 A. I started as the manager of accounting.

4 Q. What was your next position?

5 A. After that, I was promoted to, to the best of
6 my recollection, controller.

7 Q. And then?

8 A. Then to -- I have to get the sequence -- to
9 treasurer and chief financial officer.

10 Q. When did you become the chief financial officer
11 of Upsher?

12 A. To the best of my recollection, on or about
13 1993.

14 Q. Okay. Did you have any other positions or
15 titles after 1993?

16 A. Yes, in 1995, I became the vice president of
17 distribution.

18 Q. Okay, while retaining the CFO position?

19 A. That's correct. In addition, I'm also the --
20 at a certain point in time, I don't remember exactly
21 when, I became the assistant secretary for the
22 corporation as well.

23 Q. So, at all times since 1993, have you been the
24 chief financial officer of Upsher-Smith?

25 A. That's correct.

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1 Q. And what are your responsibilities as CFO?

2 A. Well, I'm responsible for seeing to the
3 collection of the receipts from the sales. I'm also
4 responsible for the disbursements and controlling the
5 disbursements; the actual accounting process and the
6 accumulation of accounting records for Upsher-Smith
7 Laboratories as well as coordinating the strategic
8 planning process.

9 Q. Okay. Sir, were there any additional
10 responsibilities you had by virtue of this position
11 vice president of distribution?

12 A. Yes, I had responsibilities for purchasing,
13 customer service and distribution.

14 Q. Sir, by virtue of being CFO, are you a member
15 of any management committees?

16 A. Yes, we have a management committee, it's an
17 executive committee, we use the name OCM. It's
18 actually an operating committee meeting, but it has
19 come to connote the executive group.

20 Q. Okay. And what's the function of this
21 executive group?

22 A. Well, the -- that group makes decisions --
23 strategic decisions as far as the company goes.

24 Q. Who are the other members of that committee?

25 A. It would include Ian Troup, chairman -- excuse

1 me, not chairman, president and COO; it would include
2 Phil Dritsas, vice president of sales and marketing;
3 Mark Robbins, vice president of scientific; Vickie
4 O'Neill, vice president of new business development; it
5 would include Mike Smith, vice president of IS; Sheila
6 Handy, director of human resources; and recently we
7 just added Troy Windt, who is director of project
8 management.

9 Q. Okay. Now, have you been a member of this OCM
10 group since 1993?

11 A. Yes, even before that.

12 Q. Even before that.

13 Sir, I want to discuss with you the Niacor-SR
14 project.

15 A. Sure.

16 Q. You're familiar with that project?

17 A. Very well.

18 Q. Okay. Sir, when did that begin?

19 A. Well, we talked about it -- to the best of my
20 recollection, we talked about it at a concept stage
21 back in the late eighties, but I believe the actual
22 clinical program or the development program, I should
23 say, started in the '91-'92 period of time.

24 Q. Was this a significant project for
25 Upsher-Smith?

1 A. Oh, it was huge. I mean, it was the largest
2 undertaking we've ever done. It -- we spent, you know,
3 over time we spent close to -- you know, to the best of
4 my recollection, \$15-\$16 million, and for the period of
5 time from 1991 to 1998, we spent four times as much on
6 that project than all the rest of the projects we
7 worked on during that entire period of time.

8 Q. What was that money used for?

9 A. Well, it was the development of the project and
10 the clinical program.

11 Q. Sir, what were the prospects or potential that
12 Upsher-Smith and its top management perceived for this
13 project?

14 A. We always thought it had a potential of at
15 least \$100 million, possibly as much as \$250 million in
16 potential.

17 Q. And what was the basis for those prospects?

18 A. We did a fair amount of research on -- market
19 research in the mid-nineties, and based upon that
20 research, there was a paper that assessed the potential
21 sales of that product.

22 Q. And what was that paper's conclusions?

23 A. The conclusion was that that -- that the
24 product could sell in the range -- as -- you know, as
25 much as \$100 million up to as much as \$400 million, but

1 basically an average range of about \$250 million.

2 Q. Sir, how did Upsher-Smith project that it could
3 achieve those levels of sales?

4 A. Well, it would have involved a significant
5 sales and marketing effort. You know, we were looking
6 at the possibility -- we were looking at the -- the
7 intended use was -- or excuse me, the intent was that
8 we would have about 100 and as much as 200 sales reps
9 out actively promoting this product to get recognition.

10 Q. Approximately how big was the sales force in
11 the mid-1990s?

12 A. I'm talking about an outside sales force, I'm
13 not even talking about the inside one, but the outside
14 sales force in the mid-nineties?

15 Q. Yes.

16 A. Was zero. We had no one in an outside sales
17 force.

18 Q. So, where was this sales force going to come
19 from to market Niacor-SR?

20 A. It was -- well, the Niacor-SR was going to
21 basically be the precipitous for basically allowing us
22 to develop that sales force.

23 Q. What sort of an investment would that involve?

24 A. Well, we are currently looking at the same
25 possibility for another product, and in today's terms,

1 we're looking at the area of \$20-\$25 million.

2 Q. Do you know what developing a sales force for
3 Niacor-SR would have cost in the mid-nineties?

4 A. In the mid-nineties? It wouldn't have been
5 significantly less. I mean, obviously you'd have to
6 discount it back some, about -- but if I had to guess,
7 a minimum of \$15-\$20 million at that point in time.

8 Q. Sir, what other things, if anything, did
9 Upsher-Smith do in developing Niacor-SR?

10 A. Well, we had -- we had a -- we developed a
11 panel of experts to help us understand the concept of
12 marketing that product, and we were basically looking
13 to utilize them when the product was going to be
14 launched to basically present to -- excuse me --
15 present to other physician groups, you know, at
16 conventions, for example, and conferences.

17 Q. All right. Why did Upsher-Smith develop this
18 panel -- is that what you called it, a panel?

19 A. Yes, or a group.

20 Q. Yes.

21 A. Well, you know, they really were -- these were
22 the top guys, the blue ribbon guys of the -- of that --
23 of that area of expertise, you know, lipidologists and
24 cardiologists of high recognition.

25 Q. Was there financial expense associated with the

1 development of those relationships?

2 A. Oh, absolutely, yeah. We -- you know, we
3 brought them in multiple times, I believe to the best
4 of my recollection two or three times, you know, just
5 to Upsher-Smith basically to get their feedback. Plus
6 we were also helping them get a better understanding of
7 niacin through -- you know, niacin through our
8 product -- another product as well.

9 Q. How were you doing that?

10 A. We were funding studies that they were working
11 on.

12 Q. Sir, were the employees and managers of
13 Upsher-Smith making any personal sacrifices to support
14 Niacor-SR?

15 A. Absolutely. Because it was such a huge product
16 and it had a -- it was -- took out a lot of the
17 profitability that would have been available for
18 multiple things, our ability to market products, so the
19 potential for growth, and from a personal note, it --
20 basically we were foregoing our own bonuses just for
21 that purpose.

22 Q. How did that work?

23 MS. BOKAT: Objection, Your Honor. This is
24 cumulative. We heard about this from Mr. Dritsas
25 yesterday afternoon.

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1 MR. CURRAN: Your Honor, I think as the CFO,
2 Mr. Kralovec has a slightly different perspective on
3 the financial aspects of the tremendous commitment of
4 resources that went into the development of Niacor-SR.

5 JUDGE CHAPPELL: Well, I'll allow it if it's a
6 different perspective, but I don't need to have the
7 same evidence introduced again.

8 MR. CURRAN: Understood, Your Honor.

9 JUDGE CHAPPELL: So, with that condition, the
10 objection is overruled.

11 BY MR. CURRAN:

12 Q. Very briefly, Mr. Kralovec, how was it that
13 employees and managers gave up bonuses?

14 A. Well, we're not like a big company. You know,
15 in big companies, basically what ends up happening is
16 that you basically get measured upon your objectives,
17 and whether the company does well or does poorly, you
18 still get a bonus. The -- that's not the situation at
19 Upsher-Smith Laboratories at all. Our bonuses have
20 always been based upon profitability. So, therefore,
21 if the profitability wasn't there, you wouldn't get a
22 bonus, or even if you did, it was a very small bonus
23 relative to what you would be -- qualify otherwise for.

24 Q. Now, sir, a moment ago you testified about
25 developing a sales force to market Niacor-SR, correct?

1 A. Yes.

2 Q. In what territory or territories was
3 Upsher-Smith contemplating marketing Niacor-SR?

4 A. Primarily in the United States. I mean, we
5 looked a little bit at the possibility of Canada and
6 Mexico, because I understand there's a naturalization
7 process where it may become easier to do it, but our
8 focus always has been the United States.

9 Q. Did Upsher-Smith have any interest in selling
10 Niacor-SR outside of the United States and the other
11 NAFTA countries?

12 A. Well, we really don't have the expertise to do
13 that, so I mean, any time we would have looked -- we
14 would have looked for an outside partner, somebody with
15 experience in those markets, just like we have in the
16 United States.

17 Q. What kind -- in the mid-1990s, what kind of
18 sales force did Upsher-Smith have in Europe and the
19 rest of the world outside of the United States?

20 A. We had none.

21 Q. Sir, did there come a time when Upsher-Smith,
22 in the mid-1990s, the second half of the 1990s, began
23 an effort to find a licensing partner in Europe?

24 A. Well, there were efforts that went on, yes, for
25 that, particularly in the 1996 period of time, we

1 actually contracted with a company out of the UK to
2 basically help us find a partner for the European --
3 the European portion of that market.

4 Q. Okay. And who was it that Upsher-Smith
5 contracted with?

6 A. The guy's name was -- to the best of my
7 recollection was David Pettit with Moreton Marketing.

8 Q. Did you have direct involvement in connection
9 with dealing with Mr. Pettit?

10 A. I don't recall directly negotiating with Dr.
11 or -- excuse me, Mr. Pettit, but I do very much
12 remember the -- discussing with Vickie O'Neill the
13 remuneration portion of that agreement.

14 Q. Okay. Did you have a role in that process?

15 A. Absolutely.

16 Q. What was your role?

17 A. Well, the original drafts -- again, to the best
18 of my recollection -- was that he wanted to have a 2
19 and a half percent -- receive 2 and a half percent of
20 whatever we received as far as -- as far as cash coming
21 into the company from the transaction that he brought
22 to us, and I said that's way too rich. I mean,
23 we're -- we really wanted -- even up front, we want to
24 get a minimal of \$15 to \$20 million. We really need to
25 scale that back. So, we went back and forth through

1 several remunerations to basically scale that back to a
2 net effect of about 1 percent.

3 Q. What was the time frame that you were having
4 these discussions?

5 A. I think it started in the fall of '9 -- '96,
6 and actually we concluded that in December of '96.

7 Q. And was Mr. Pettit and Moreton engaged by
8 Upsher-Smith?

9 A. Yes, shortly afterwards, they basically went
10 out and solicited interest from multiple groups, many
11 companies.

12 Q. Do you have an understanding as to exactly what
13 he did?

14 A. Well, he was -- he -- these kind of brokers
15 basically, what they're capable of doing is they have
16 lots of contacts in the industry, and basically he was
17 using his contacts to basically bring forth our
18 product. So, we basically helped him by preparing a
19 group of materials that he circulated to basically
20 create that interest.

21 Q. And how did he do?

22 MS. BOKAT: Objection, Your Honor. I don't
23 think we have any foundation for this witness, the
24 chief financial officer, having been involved with Mr.
25 Pettit beyond the contract between Upsher and Moreton.

1 MR. CURRAN: I'd be happy to lay a further
2 foundation, Your Honor.

3 JUDGE CHAPPELL: Right, this is not an expert
4 witness, is it?

5 MR. CURRAN: Correct.

6 JUDGE CHAPPELL: So, with the proper
7 foundation, I'll allow him to testify about his
8 perception.

9 MR. CURRAN: Thank you, Your Honor.

10 JUDGE CHAPPELL: And with that, I'll
11 overrule -- actually, I'm sustaining the objection at
12 this point until a proper foundation is laid.

13 MR. CURRAN: Very good, Your Honor.

14 BY MR. CURRAN:

15 Q. Mr. Kralovec, let's take this in baby steps,
16 okay?

17 A. Sure.

18 Q. Do you have -- did you have an understanding as
19 to how David Pettit and the Moreton Companies were
20 doing in their efforts to identify a licensing partner?

21 A. I was receiving input from Vickie O'Neill as
22 far as how Dr. -- excuse me, Mr., I keep saying Dr. --
23 Mr. Pettit was doing.

24 Q. Okay. What did Ms. O'Neill tell you about how
25 he was doing?

1 MS. BOKAT: Objection, hearsay.

2 MR. CURRAN: Your Honor, I'm not offering this
3 for the truth of the matter. I'm offering this to --
4 because it's relevant to the state of mind of the OCM,
5 the executive committee of Upsher-Smith, in this time
6 frame.

7 MS. BOKAT: About what?

8 MR. CURRAN: About how their marketing efforts
9 were going in Europe.

10 JUDGE CHAPPELL: So, whatever Ms. O'Neill said
11 to him, you don't care if it's true or false?

12 MR. CURRAN: Correct.

13 JUDGE CHAPPELL: But that it was said and that
14 he acted on it?

15 MR. CURRAN: Correct.

16 JUDGE CHAPPELL: Overruled.

17 MR. CURRAN: Your Honor, Ms. O'Neill -- we
18 expect Ms. O'Neill to testify next week, and she can be
19 cross examined, and at that point in time we'll address
20 the truth of the matter.

21 BY MR. CURRAN:

22 Q. Okay, what did Ms. O'Neill tell you and the
23 other members of the executive committee about how the
24 efforts were going by Moreton and Mr. Pettit?

25 A. Well, she said that there was strong interest,

1 that CDAs were being executed, that they were going out
2 to make presentations to a group of companies, and that
3 she was very optimistic.

4 Q. Sir, are you familiar with a company called Kos
5 Pharmaceuticals?

6 A. Very well.

7 Q. Sir, did there come a time when executives from
8 Kos approached Upsher-Smith in connection with a -- the
9 licensing of intellectual property?

10 A. Yeah, it was actually very interesting when it
11 happened. They, unbeknownst to us -- I mean, we
12 knew -- first of all, let me say first, I knew Kos from
13 the standpoint that we knew that they were developing a
14 competing product to our Niacor-SR, but they actually
15 came to us when they were about to go public and said,
16 we need to license your products because we have this
17 patent interference issue with the Trade Office, and so
18 therefore, we have to -- we really need to create a
19 license here.

20 Q. So, they came to you?

21 A. Yeah, just out of the blue.

22 Q. And -- well, who came to Upsher-Smith?

23 A. It was actually the president, I'm trying to --
24 I think it's Dan Bell. I think it's Dan Bell. Mr.
25 Bell, and I think it's Dan.

1 Q. Okay. And were you personally involved in
2 these discussions?

3 A. Not the initial one, but I was definitely
4 involved with the negotiations of the cross-license.

5 Q. Okay. Was a cross-licensing agreement
6 ultimately reached between Upsher-Smith and Kos?

7 A. Yes, it was.

8 Q. Did anybody -- well, did money change hands?

9 A. Yes, there was -- there were actually up-front
10 payments, there were -- there was a -- and there was a
11 royalty stream as well.

12 Q. Who paid whom?

13 A. They paid us.

14 Q. Both the up-front portion?

15 A. That's correct.

16 Q. And the royalty portion?

17 A. To the best of my recollection, it was like \$3
18 million in staggered payments -- I keep doing that --
19 staggered payments over time, as well as a royalty
20 stream that continues to this day.

21 Q. So, Upsher-Smith has been receiving royalty
22 payments from Kos for the last several years?

23 A. Yes -- well, since they launched the product.
24 They launched the product in -- again, the best of my
25 recollection, it was in the fall of 1997, and we've

1 been receiving payments since then, and for most years
2 it's been about \$2.5 million.

3 Q. Sir, did Kos eventually go public?

4 A. They did, very shortly afterwards. As a matter
5 of fact, like I said, they -- because of this, they
6 needed to clean up their prospectus, and as soon as
7 they got the prospectus cleaned up, they went public.

8 Q. Sir, I'd like to direct your attention to the
9 booklet that I've passed out and the first tab under
10 that.

11 Your Honor, this document is already admitted
12 into evidence.

13 JUDGE CHAPPELL: Thank you.

14 BY MR. CURRAN:

15 Q. Mr. Kralovec, do you see that exhibit?

16 A. Yes.

17 Q. Do you see in the bottom right where it says
18 USX 535?

19 A. Yes.

20 Q. What is this exhibit?

21 A. Well, this is an analyst's report from an
22 investment banking firm of Dillon Read.

23 Q. Okay. On Kos Pharmaceuticals?

24 A. On Kos Pharmaceuticals.

25 Q. Okay. Where did this come from?

1 A. This came out of my files. It was sent to me
2 by Mr. Evenstad.

3 Q. And who is he?

4 A. Oh, sorry, Mr. Evenstad is the chairman and
5 chief executive officer of Upsher-Smith Laboratories.

6 Q. How do you know this came out of your files?

7 A. Because I always put an "F" so my secretary
8 knows where to file it, so I put "F" relative to the
9 file under Kos Pharmaceuticals.

10 Q. Sir, this appears to have two copies of this
11 Dillon Read analyst report as part of this exhibit.

12 A. That's correct.

13 Q. Is that a copying mistake that my law firm
14 made?

15 A. No. No, it would have been -- this would have
16 been another copy of -- many times when Ian Troup, the
17 president and chief operating officer of Upsher-Smith
18 Laboratories, would get documents of a financial
19 nature, reports and those kinds of things, he would
20 circulate them to me as well, and if I didn't remember,
21 I'd stuff them into the same file. So, put it this
22 way, the net effect of that is that lots of people were
23 looking at Kos Pharmaceuticals from our company.

24 Q. Well, why were people from Upsher-Smith looking
25 at Kos Pharmaceuticals and its stock performance?

1 A. Well, we had -- it was tied to our royalty
2 streams. We were to get a royalty as soon as they went
3 public -- I mean, excuse me, as soon as they started
4 selling their product. So, it was important for us to
5 monitor them on a continual basis. I personally would
6 pull their 10-Ks and 10-Qs, which are quarterly
7 statements, financial statements, just to find out what
8 they were reporting, just to match it up against our
9 royalty stream.

10 Q. Were there any other reasons why folks at
11 Upsher-Smith might have been interested in the Kos
12 stock price or market capitalization?

13 A. Well, again, they had what we perceived as
14 being a virtually identical product to ours, and we
15 wanted to see how well they were going to do, how well
16 they were going to do with that product.

17 Q. Sir, what's the date on this stock analyst
18 report?

19 A. Hold on one second.

20 Ah, the report is as of April 21st, 1997.

21 Q. Do you recall roughly when you received this?

22 A. Shortly afterwards.

23 Q. Okay. Sir, did you find anything in this
24 analyst report to be notable, particularly notable?

25 A. Yes, on page -- it would be page USL 11515.

1 Q. Yes, what on that page?

2 A. It talks about the fact that they believed that
3 they could sell -- interestingly, about the same number
4 we thought -- \$250 million of this product by year
5 2001.

6 MS. BOKAT: Your Honor, could I ask for a
7 clarification? It's my recollection that this document
8 was offered not for the truth but for the fact that
9 analysts were reporting this information.

10 MR. CURRAN: Correct, correct, and it goes to
11 the state of mind of what the Upsher-Smith executives
12 were thinking at the time they engaged in the June
13 17th, 1997 transaction with Schering.

14 MS. BOKAT: So, this witness, to the extent he
15 testifies about the contents of the document, that
16 testimony isn't offered for the truth of the statements
17 in the analyst's report?

18 MR. CURRAN: Correct, it's being offered to
19 rebut the allegation that the June 17th, 1997 agreement
20 was somehow a sham.

21 May I proceed, Your Honor?

22 JUDGE CHAPPELL: Yes.

23 BY MR. CURRAN:

24 Q. I forget where we left off, Mr. Kralovec.

25 A. We were talking about the fact that this report

1 basically said that they felt that Kos with a very
2 similar product had the capability of selling \$250
3 million of their product by 2001.

4 Q. Now, sir, do you know whether or not your
5 discussions of the cross-licensing deal with Kos were
6 before or after this analyst report?

7 A. I know it started before. I don't -- and I'm
8 trying to remember when we finally signed that. To the
9 best of my recollection, this should have been after,
10 but I'm not positive on that.

11 Q. Sir, do you know when Kos went public?

12 A. Well, I believe it was before this report, so
13 that make -- it would be logical that -- because I know
14 they had to get that cross-license signed before they
15 could go public, so I would say that then based upon
16 that that it -- it should have been after the signing
17 of the agreement.

18 Q. Sir, when reaching the cross-licensing
19 agreement with Kos, did that transaction affect
20 Upsher-Smith's ability to license Niacor-SR outside the
21 United States?

22 A. No. As a matter of fact, we specifically were
23 addressing that issue when we created that license.

24 Q. And how did you address that issue?

25 A. We -- there's a specific provision, to the best

1 of my knowledge, a specific provision right within that
2 cross-license.

3 MR. CURRAN: Your Honor, it's your pleasure
4 whether I continue with this witness or you want to
5 take a break.

6 JUDGE CHAPPELL: No, let's take a morning
7 recess. We'll adjourn until 11:40.

8 (A brief recess was taken.)

9 JUDGE CHAPPELL: Mr. Curran, you may proceed.

10 MR. CURRAN: Thank you, Your Honor.

11 BY MR. CURRAN:

12 Q. Mr. Kralovec, let me see if I can set our place
13 here. We're in the spring of 1997, and Upsher-Smith at
14 that point in time had already engaged Mr. Pettit to
15 find a licensing partner in Europe, correct?

16 A. That's correct.

17 Q. And it was in the spring of '97 when Kos and
18 Upsher-Smith had the negotiations on the
19 cross-licensing agreement, correct?

20 A. Yes, early spring.

21 Q. And I believe you've testified that that
22 agreement did not affect Upsher's ability to find a
23 licensing partner outside the United States, correct?

24 A. That's correct.

25 Q. Did Upsher, in fact, continue to search for a

1 licensing partner after the Kos cross-licensing
2 transaction?

3 A. Yes, we were actively looking -- we were
4 actively looking for a partner in the -- in Europe.

5 Q. And was that a continuation with Moreton and
6 Mr. Pettit?

7 A. Yes.

8 Q. Sir, did there come a time when Upsher-Smith,
9 in fact, found a licensing partner for Niacor-SR?

10 A. Yes, for everything but NAFTA with
11 Schering-Plough.

12 Q. Okay. And you're referring to the June 17th,
13 1997 agreement?

14 A. Yes, I am.

15 Q. Sir, were you involved personally in the
16 negotiations of that agreement?

17 A. I didn't have direct contact, negotiating
18 contact with the Schering people. I mean, other than I
19 may have shook hands with one of them when they were in
20 our offices, I really had no direct contact with them,
21 but I was definitely talking to Ian about
22 reasonableness terms as far as the agreement and cash
23 flow issues.

24 Q. And by "Ian," you're referring to Mr. Troup?

25 A. Mr. Troup.

1 Q. Can you get more specific as to what matters
2 you discussed with Mr. Troup that related to the
3 negotiations of that agreement?

4 A. Well, it was -- specifically I remember the
5 up-front payments, you know, the group of up-front
6 payments that were received, the 28, the 20 and the 12,
7 just from a logical standpoint, that it's much better
8 to have money earlier versus later.

9 Q. Is that something you discussed with Mr. Troup?

10 A. Yes, that's correct.

11 Q. Okay. What was the context of that discussion?

12 A. Well, he had -- you know, there was some
13 discussion about the \$60 million, and I said, you know,
14 there was a proposal I understood at some point where
15 it was going to be 20/20/20, 20 on signing, 20 at the
16 first anniversary, 20 at the second anniversary, as a
17 complete structure, and I said, you know, if we could
18 move some of that up closer, it would be better from a
19 cash flow standpoint and would add value.

20 Q. Why would that add value?

21 A. Well, because money sooner is better than
22 later, and also you want to make sure, you know, you
23 don't want to have any issues outstanding and have to
24 worry about getting those funds.

25 Q. Sir, did there come a time when you saw the

1 final agreement?

2 A. Yes, I saw the final agreement shortly after it
3 being signed.

4 Q. And what was your reaction to the licensing
5 provisions of that agreement?

6 A. I thought it was great that we found an
7 international partner to basically license out that
8 group of products.

9 Q. Did anything about the agreement give you any
10 concerns?

11 A. Well, the one provision -- if you look at each
12 of those, at least if you look at about -- I think
13 there were six products licensed, five of those six, if
14 we were to sell them to Schering, we had to sell them
15 to them for cost, and I had concern from the standpoint
16 that it really had not -- the detail on that from the
17 standpoint of how much we were going to sell to them
18 and the -- how much it was going to consume our
19 capacity was a little bit of a concern to me.

20 Q. Okay. Sir, why is it a concern for Upsher to
21 take on some sort of production obligation?

22 A. Well, it's a lost opportunity cost. If we're
23 giving -- if we're manufacturing product for them and
24 at cost, we can't manufacture products we want for
25 profit. So, therefore, you're losing some economic

1 value just from the standpoint of having to produce
2 those products.

3 And like I said, it could be done -- because
4 there wasn't any specific terms, it could be done at a
5 moment's notice, so therefore we would have had to
6 potentially interfere with our customer service levels
7 to provide product to them.

8 Q. Okay. Sir, I want to switch gears a little bit
9 for a moment and discuss the patent litigation.

10 Sir, was there patent litigation between
11 Upsher-Smith and Schering-Plough ever?

12 A. Yeah, yeah, there was a major dispute between
13 us.

14 Q. When did that start?

15 A. To the best of my recollection, it was December
16 of 1995.

17 Q. And what happened then?

18 A. Well, the -- there was a -- they basically sued
19 us, and we went through a process, a very long and
20 painful process of trying to resolve that dispute.

21 Q. What was the dispute about?

22 A. My understanding was that we had formulated a
23 product and they said that it infringed -- and I'm not
24 talking about from a legal standpoint, but I understand
25 there was something where we were competing with their

1 or we were interfering with their patent.

2 Q. You said that lawsuit started in December of
3 '95?

4 A. To the best of my recollection.

5 Q. Okay. What's your understanding of how it
6 proceeded?

7 A. Well, it was -- it was very hostile. I mean,
8 the -- I remember that we had a set of attorneys that
9 we wanted to use, and they were able to somehow kick
10 the attorneys out, and we had to go find another set of
11 attorneys. There was a process where there was -- they
12 were supposed to produce some documents, and we were
13 producing our documents we felt on a timely basis, but
14 there seemed to be delays in that process. The judge
15 was asked to make some rulings, and that took much
16 longer than we planned. So, everything seemed to slow
17 down significantly.

18 Q. Sir, what's your understanding as to what was
19 at stake in this litigation?

20 A. Well, my understanding was that we would not be
21 allowed to go to market until we -- unless we resolved
22 this dispute.

23 Q. Go to market with what?

24 A. Oh, excuse me, with our M20 product.

25 Q. Sir, what was the financial impact of this

1 litigation on Upsher-Smith?

2 MS. BOKAT: Objection, Your Honor. I think
3 this question is getting into the area of Upsher's
4 financial condition, and we had an agreement with
5 counsel for Upsher that they would not provide certain
6 documents in response to a discovery request in return
7 for a commitment not to raise Upsher's financial
8 condition as a justification or a reason for entering
9 into the agreement with Schering-Plough.

10 MR. CURRAN: Well, Your Honor, I don't even
11 think we need to debate the terms of the agreement
12 between the parties, because I don't think this
13 question or any questions I intend to ask relate to the
14 financial condition of Upsher-Smith. I think I just
15 asked what the financial impact of the litigation was.
16 All I'm trying to elicit here is how much Upsher had to
17 pay for defending this patent litigation.

18 JUDGE CHAPPELL: Well, if there was an
19 agreement between the parties, I'm not -- I haven't
20 seen it. If I have to get in the middle of
21 interpreting an agreement that the parties formed, I
22 will, but I would hope that the parties can agree what
23 crosses the line.

24 MR. CURRAN: Yeah, I'll tell you what, Your
25 Honor, I'm prepared to make a representation that

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1 nothing I elicit from Mr. Kralovec may be used to
2 support an argument that Upsher's financial condition
3 justified anything. I just want to elicit facts
4 relating to the circumstances and conditions prevailing
5 at the time of the June 17th, 1997 agreement.

6 JUDGE CHAPPELL: Well, as the chief financial
7 officer, this gentleman has a perspective unlike
8 anybody else at the company, and I can understand
9 generally how that from what I've heard is not going to
10 I guess violate the agreement, but what I'm going to do
11 is allow Ms. Bokat to object after she hears an answer,
12 and then we'll decide whether I need to disregard it.

13 MR. CURRAN: Very good, Your Honor.

14 JUDGE CHAPPELL: Do you want Susanne to read
15 back the pending question?

16 MR. CURRAN: I'm pleased to spare her of that
17 responsibility. Thank you, Your Honor.

18 BY MR. CURRAN:

19 Q. Mr. Kralovec, what were the financial
20 implications of this litigation -- the financial impact
21 of this litigation upon Upsher-Smith?

22 A. We spent nearly \$3 million on that litigation.

23 Q. Over what time frame?

24 A. From 19 -- from December of 1995 through June
25 of 1997.

1 Q. Sir, what effect did the litigation have on
2 Upsher's ability to market Klor Con M20?

3 A. I'm sorry, could you repeat the question?

4 Q. Sure. What effect --

5 MS. BOKAT: Excuse me, Your Honor. Is Mr.
6 Curran asking for a legal opinion from this witness,
7 because I believe he's not a lawyer.

8 MR. CURRAN: Well, Ms. Bokat is absolutely
9 correct, this is not a lawyer who's testifying. He's
10 the CFO. I'm asking the CFO of Upsher-Smith what
11 effect -- I'll be happy to say what's his understanding
12 of the effect of the litigation on the sales of Klor
13 Con M20 if that would obviate the objection.

14 JUDGE CHAPPELL: Well, in my mind, his
15 understanding is his perspective based on his position
16 within the corporation. You know, a lot of people use
17 "I understand" when they don't really want to be honest
18 about or they don't really know what they are talking
19 about. It's a technique I used to hear all the time as
20 a prosecutor. A witness would say, well, I understand
21 that somebody did something. That's not my
22 interpretation of somebody's understanding. I just
23 want to make that clear.

24 His understanding is from his perspective
25 within the company or from where he sat when events

1 occurred. We know he's not a pharmacist, I heard that.
2 We know he's not a lawyer.

3 MS. BOKAT: And we know he's not the marketing
4 person.

5 JUDGE CHAPPELL: That's right. So, with that
6 perspective, I'll overrule the objection at this time.

7 MR. CURRAN: Thank you, Your Honor.

8 BY MR. CURRAN:

9 Q. Okay, Mr. Kralovec, as a CPA and as the chief
10 financial officer of Upsher-Smith, what's your
11 understanding as to the effect the litigation had as to
12 Upsher's ability to sell Klor Con M20?

13 A. The settlement?

14 Q. No, the --

15 A. I'm sorry.

16 Q. -- the litigation.

17 A. Oh, the litigation. Well, it was a financial
18 strain from our -- from our standpoint, that it -- we
19 were unable to -- because we were spending the money on
20 that, we were unable to market -- spend as much money
21 as we would have liked on marketing or developing other
22 products or paying bonuses.

23 Q. Sir, did there come a time where you made any
24 decision, where you participated in the making of a
25 decision, as to whether or not Upsher-Smith would

1 market Klor Con M20 before the end of the litigation?

2 A. Yes.

3 Q. What was that decision and what was your role
4 in that decision?

5 A. The group that was looking at the process of
6 the launch of that product had requested IPC, our
7 contract manufacture, to start preparing validation
8 batches as well as we were looking at the possibility
9 of holding open a period of time for production of the
10 product, and I specifically went to Scott Gould, who
11 reported to me, and said we're not going to do that,
12 because we don't know what the outcome of the trial's
13 going to be.

14 Q. Why did you make that decision?

15 A. Because to launch a product when you don't --
16 when we didn't have resolution would have been
17 financial suicide in my mind.

18 Q. Why did you have that view?

19 A. The -- my understanding was that if we had lost
20 the case, it could have been a significant financial
21 obligation for us to pay as far as damages go.

22 Q. Sir, how did the litigation end?

23 A. We signed an agreement in -- June 17th of 1997.

24 Q. And that was -- the patent was resolved in the
25 same agreement --

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1 A. There were -- my understanding was there was
2 two agreements in one. It was -- basically there was
3 this resolution of this dispute and the right -- and
4 the licensing of the products.

5 Q. What was your understanding of the effect of
6 the patent settlement upon Upsher-Smith?

7 A. Well, we had a date certain that we knew when
8 we could launch. So, basically we knew that we could
9 launch on or -- you know, on September 1st of 2001.

10 Q. Why was that relevant or important?

11 A. Well, it allowed us basically -- it does two
12 things. One is it sets a date so you can start
13 planning to that date, you know, so you can make sure
14 that you have capacity and make sure that you can
15 manufacture the product so you can have a successful
16 launch. So, that's very helpful.

17 Q. Sir, are you aware of any circumstances under
18 which Upsher-Smith could have come to the market with
19 the M20 under the settlement before September 1st of
20 '01?

21 A. To the best of my recollection, there was
22 something, depending on the actions of Schering-Plough
23 and the way they -- something that they did, there was
24 a possibility that they -- we could come to the market
25 earlier.

1 Q. Sir, are you generally familiar with the terms
2 of the patent settlement between Upsher-Smith and
3 Schering-Plough?

4 A. I'm familiar with the agreement if that's what
5 you mean.

6 Q. All right. Are you familiar with the terms --

7 A. Of the agreement?

8 Q. -- of the agreement?

9 A. Yes, in general.

10 Q. And under that agreement, Upsher-Smith, barring
11 the conduct you referred to by Schering --

12 A. Yes.

13 Q. -- was not allowed to come on the market with
14 the M20 product until September 1st of '01, correct?

15 A. That's correct.

16 Q. Sir, are you aware of language in the agreement
17 referring to "any other microencapsulated potassium
18 chloride tablet"?

19 A. I saw that language in the agreement.

20 Q. Okay. And what was your understanding of what
21 that meant in the agreement?

22 A. I got the impression that basically they just
23 didn't want to be backdoored, and what I mean by that
24 is it's -- you wouldn't want to -- you wouldn't want to
25 have the -- you wouldn't want to have them -- have us

1 producing a similar product -- an identical product
2 with a different name.

3 MR. CURRAN: Hold on, I think Ms. Bokat has an
4 objection, so I am going to ask that you stop.

5 MS. BOKAT: I have an objection and I move to
6 strike the last answer. He testified in that last
7 answer about Schering's intent with respect to this
8 provision, which I don't think we've seen any
9 foundation that he can testify about, and he's
10 interpreting a clause of the contract, which is asking
11 him for a legal interpretation.

12 JUDGE CHAPPELL: I'll sustain that. I will
13 allow this witness to tell us I suppose the CFO
14 perspective, but I don't need to know his understanding
15 of the agreement.

16 MR. CURRAN: Very good, Your Honor, and I
17 certainly didn't mean to elicit a legal opinion or
18 testimony as to Schering's intent.

19 JUDGE CHAPPELL: And I will disregard the last
20 response. So, your -- if I haven't said so, your
21 objection's sustained.

22 BY MR. CURRAN:

23 Q. Mr. Kralovec, is the Klor Con M20 product sold
24 today?

25 A. Yes, it is.

1 Q. When did it start being sold?

2 A. We -- our first sale was September 1st, 2001.

3 Q. Is the Klor Con M10 product being sold today?

4 A. Yes, it is.

5 Q. When did that start being sold?

6 A. September 1st, 2001.

7 Q. Sir, I want to ask you a series of questions
8 dealing with Upsher-Smith's efforts and activities
9 leading up to the launch of those products.

10 A. Okay.

11 Q. Okay. First of all, can you give me a general
12 overview of what Upsher-Smith had to do to be ready to
13 launch those products?

14 A. Yes, we had to -- we had to build capacity in
15 our facilities. We had to buy equipment in our
16 facilities. We had to build inventories in our
17 facilities. We also lent money to IPC, the contractor
18 I was talking about, so they could add space and
19 equipment and so they could help us build our
20 inventories.

21 Q. Sir, can you tell me generally how Klor Con M20
22 gets manufactured?

23 A. Sure. We buy the crystals of salt, potassium
24 chloride salt, from a company called Reheis. It's
25 shipped to IPC, which is our contract manufacturer.

1 They take a -- they take basically a -- what's called a
2 fluid bed dryer, and they apply a coating onto the
3 crystals, which is the sustained releasing process --
4 and I'm not talking from a scientific term, but my
5 understanding of it -- and then we take those coated
6 crystals, bring them to our facility, mix them with
7 additional ingredients, put them on a press and press
8 them into a tablet, take them to a bottling line and
9 put them into -- into -- or a bottling line or Unidose
10 line to basically package them off.

11 Q. Okay. Now, you're the CFO. How do you know
12 the details of the production process?

13 A. Well, I've been involved with the purchasing
14 and distribution process, so I mean, again, that's my
15 general understanding.

16 Q. Well, have you ever been to the IPC
17 manufacturing facility?

18 A. I have, multiple times.

19 Q. Why have you gone there?

20 A. It was part of the -- I was involved with the
21 contracting as far as IPC goes, when we lent them the
22 money and the manufacturing contract that was
23 associated with it. I was also very concerned about
24 their ability to deliver their facility on time, so we
25 were -- I was down there several times just to make

1 sure that the facility was going to be ready when we
2 needed it.

3 Q. Why did you -- why did Upsher-Smith lend money
4 to your contract manufacturer?

5 A. They -- we were told that they had used up
6 their lines of credit and that they -- that they did
7 not have the capacity to manufacture the product that
8 we needed. So, therefore, they needed to expand their
9 capacity, and they said the only way they could do that
10 is if we would lend them the money.

11 Q. And how much did you say you lent IPC?

12 A. \$2,750,000.

13 Q. And specifically what was that for?

14 A. Well, it was for -- again, it was an expansion
15 of their facility. They created a -- what we call a
16 tank farm, where they would have the solvent that would
17 be used in the manufacture or the process. They
18 created large kettles for making the solution that
19 would be applied to the salt. They renovated a room
20 for -- and put in a new what's called fluid bed dryer,
21 which is the piece of equipment where the chemical gets
22 applied to the -- excuse me, the coating gets applied
23 to the salt.

24 They -- as part of that process, they had to
25 upgrade their HVAC systems, their -- the air handling

1 systems, the oxidizer, which is what burns off the
2 alcohol after it's been -- after the chemical's been
3 applied. Gosh, I'm trying to remember what else.
4 Those are -- those are the major pieces that I remember
5 that we financed.

6 Q. Okay. Did you say earlier that Upsher-Smith
7 also had to have expansion in order to manufacture the
8 Klor Con M20 and the M10?

9 A. Yes, we put 17,000 square feet of facility onto
10 our building, which basically included adding warehouse
11 space for the raw materials, new processing labs, you
12 know, areas of -- for the facility, as well as a
13 shipping dock was added.

14 In addition, we added equipment, which included
15 a press, tote handling equipment for material handling,
16 and another mixer as well, and a packaging line.

17 Q. Now, Upsher-Smith has been manufacturing
18 potassium supplements for years, right?

19 A. Yes, we have.

20 Q. And Klor Con M20 and Klor Con M10 are
21 additional potassium supplements, correct?

22 A. That's correct.

23 Q. So, why was it necessary for there to be
24 expansion in order to sell these two new products?

25 A. Well, when we definitively decided what we were

1 going to -- needed for our launch quantities, it was
2 determined that we didn't have the capacity to
3 manufacture this product with -- and manufacture all
4 the other products that we were manufacturing at the
5 same time.

6 Q. Now, sir, how long did it take from start to
7 finish --

8 A. Well, there --

9 Q. -- to -- let me finish.

10 A. I'm sorry.

11 Q. How long did it take from start to finish to do
12 what was necessary to launch Klor Con M20 and Klor Con
13 M10 on September 1st, 2001?

14 A. There were activities going on, you know, even
15 in the 1997 period of time, but the intensive amount of
16 activity from the planning to the building of the
17 capacity to the building of the inventory took to the
18 best of my knowledge -- best of my recollection two to
19 two and a half years.

20 Q. Sir, you referred to the 1997 time frame.

21 A. Yes.

22 Q. In 1997, spring let's say, what were your
23 expectations or Upsher-Smith's expectations as to how
24 long it would take to do what was necessary to launch
25 the M20 or the M10?

1 A. Well, that's a hard question to answer, because
2 we really didn't have a definitive decision on what we
3 were going to use for our launch quantities. We had
4 played with some numbers, but nothing had been
5 officially committed. So, to say that we knew -- I
6 mean, we were able -- capable and we had the capacity
7 to manufacture some product, but as far as saying, you
8 know, all the things that went on afterwards, we didn't
9 know that until we could define what that forecast was.

10 Q. Well, now, you had manufacturing capacity
11 already, correct?

12 A. Yes, we did.

13 Q. Couldn't you just use that existing
14 manufacturing capacity to manufacture the M20 or the
15 M10?

16 A. Sure, but why would you do that, because what
17 you'd end up doing is potentially losing sales on -- or
18 not having the ability to manufacture sales on some of
19 your other products; therefore, you've got a lost
20 opportunity cost from the standpoint of the profit that
21 could be generated, not even am I addressing the issue
22 of our jeopardizing our customer service levels.

23 If anything, Upsher-Smith has always been
24 focused on customer service, our ability to deliver the
25 products as the inventories come in -- excuse me, as

1 the orders come in. So, from that standpoint, that --
2 we would not have wanted to jeopardize our customer
3 service levels.

4 Q. Sir, you've already described the various
5 things Upsher-Smith had to do to launch the M20 and the
6 M10 in September of '01, correct?

7 A. Yes.

8 Q. Why didn't you do all of that stuff in the
9 early 1990s or the mid-1990s?

10 A. Well, it -- why would we -- I mean, until we
11 knew what we definitively wanted to manufacture, I mean
12 you can't go through all those other steps. That's
13 kind of a -- you know, it's a process you've got to
14 build after you say, all right, here's the end result,
15 I want -- you know, I want 91 million tablets, you work
16 your way back to say what does that mean as far as
17 building a facility, whether you have the capacity or
18 the equipment.

19 Q. Did you consider expansion and a launch ramp-up
20 in the early or mid-1990s?

21 A. Well, there was definitely discussion about the
22 fact -- I know when George Tomaich was there, that he
23 had said that we would need to expand our facilities if
24 we were going to -- if the demand was as large as he
25 had perceived it would be at the time. So, there was

1 discussion of it.

2 Q. Why didn't you do it?

3 A. Because we were -- well, I mean, the real
4 answer is until we knew we had a definitive conclusion
5 to the trial and we knew that we were -- you know, that
6 we could launch the product, we weren't willing to
7 commit a lot of resources to it.

8 Q. Now, sir, on September 1st of '01, Upsher-Smith
9 launched both the M10 and the M20 products?

10 A. Yes, that's correct.

11 Q. How were you able to go forward with the M10 --
12 well, let me restate that.

13 Okay, we've already discussed the M20 patent
14 litigation and patent settlement, correct?

15 A. Yes.

16 Q. Was the M10 product subject to the patent
17 litigation?

18 A. My understanding was no, it was not part of
19 the -- part of the litigation.

20 Q. Sir, I want to switch gears. I want to discuss
21 communications between you and Schering-Plough after
22 June 17, 1997.

23 A. Okay.

24 Q. Okay. Sir, did you have communications with
25 representatives of Schering-Plough after June 17th,

1 1997 relating to the products that Upsher-Smith
2 licensed to Schering-Plough?

3 A. Yes, we -- shortly afterwards, we received a
4 supplemental agreement which incorporated a
5 manufacturing agreement.

6 Q. Sir, I'd like to direct your attention to the
7 document under tab 2 in your book.

8 A. Yes.

9 Q. Okay, please take a moment to review this
10 exhibit. For the record, I'll note it's USX 452.

11 A. Yes.

12 Q. Okay. Sir, what is this document?

13 A. To my best recollection, to the best of my
14 recollection, this is the -- this is the draft document
15 that they sent -- Schering sent to us as far as -- as
16 far as the amended agreement.

17 Q. Okay. Sir, there's handwriting in the upper
18 right of this -- of the first page of this document.
19 Do you see that?

20 A. Yes.

21 Q. Whose handwriting is that?

22 A. That's my handwriting. It's -- again, this is
23 so my assistant knew where to file this, to create a
24 file folder for this.

25 MR. CURRAN: Your Honor, I move for the

1 admission of USX 452 into evidence.

2 MS. BOKAT: No objection.

3 MS. SHORES: No objection, Your Honor.

4 JUDGE CHAPPELL: USX 452 -- is that right?

5 MR. CURRAN: That's correct, Your Honor.

6 JUDGE CHAPPELL: USX 452 is admitted.

7 (USX Exhibit Number 452 was admitted into
8 evidence.)

9 BY MR. CURRAN:

10 Q. Mr. Kralovec, did this document come to your
11 attention on or around late June, early July 1997?

12 A. Yes.

13 Q. Did you read it at that time?

14 A. Extensively.

15 Q. Do you recall what your reaction was?

16 A. Well, there were two provisions I was concerned
17 about. One was the fact that they appeared to be
18 trying to change the deal that had been struck as far
19 as the royalty stream goes, and from a financial
20 standpoint, I was concerned that they were trying to
21 extend what would be considered -- I would consider
22 normal terms for payment.

23 Q. All right, let's break that up into two parts.
24 The first concern you identified dealt with royalty
25 payments?

1 A. Yes. If you look at -- let me find it here --
2 if you look at USL 02011.

3 Q. And what part of that page are you trying to
4 point us to?

5 A. If you look at A.3 of that page, it refers to
6 the term of the royalty payments.

7 Q. Yes.

8 A. And there was this -- what appeared to me to be
9 a shortening of the term to either the length of the
10 patent or ten years, the ten-year anniversary. So, it
11 appeared to be a shortening of the potential payments
12 that we would receive.

13 Q. Sir, did you prepare comments on this
14 agreement?

15 A. Yes, after it had been circulated and I
16 accumulated all of the comments of the people, I
17 redrafted or marked up a copy of this agreement.

18 Q. Okay. Sir, can you refer to the document under
19 tab 3, please.

20 A. Yes.

21 Q. Okay, please take a moment to flip through that
22 document. For the record, I'll note it's USX 732.

23 A. Yes.

24 Q. Is this the mark-up of comments that you
25 referred to?

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1 A. That's correct, all of the writing on the sides
2 are my -- are my -- is my handwriting.

3 MR. CURRAN: Your Honor, I move for the
4 admission of USX 732 into evidence.

5 MS. BOKAT: No objection.

6 MS. SHORES: No objection.

7 JUDGE CHAPPELL: USX 732 is admitted.

8 (USX Exhibit Number 732 was admitted into
9 evidence.)

10 BY MR. CURRAN:

11 Q. Mr. Kralovec, did you address the point on
12 royalties that you referred to a moment ago in these
13 comments?

14 A. Yes, I did. If you look at SP 1200204, and if
15 you look at the A.1 term, you'll see that we crossed
16 out that language as far as trying to shorten the term.

17 Q. Okay, I'm sorry, what paragraph are you looking
18 at?

19 A. A.3.

20 Q. A.3.

21 A. And it -- can you see where it says, "or the
22 tenth anniversary of the date" was crossed out?

23 Q. Got you. And why did you cross that out?

24 A. Because we thought that it was changing the
25 deal.

1 Q. In what respect?

2 A. Well, it was shortening the term of the royalty
3 payments that would be received from Niacor-SR.

4 Q. Sir, you also referred to another concern you
5 identified, another specific concern you identified
6 with respect to Schering's proposed draft.

7 A. Yes. That was in reference to the payment
8 term -- let's see if I can find that page. Oh, if you
9 look at SP 1200207.

10 Q. Yes.

11 A. This -- it was the -- it was the delivery
12 terms, and originally we were trying to mark this up a
13 little bit and trying just to come up with certain of
14 the terms, you can see where I originally had 60 and I
15 crossed it off with 30, and after going through this
16 document enough, we decided that there was too many of
17 the terms that were inconsistent with our standard
18 manufacturing agreement. So, if you go to SP 1200217,
19 you will see that's the start of our standard
20 manufacturing agreement, and that's what the subsequent
21 pages are.

22 Q. So, you incorporated that in your responsive
23 comments?

24 A. Yes, that's correct.

25 Q. Sir, were there further communications that you

1 had with Schering representatives regarding these
2 documents?

3 A. There were -- was at least one or two other
4 reiterations of this where they sent us comments -- to
5 the best of my recollection, one or two reiterations
6 where they sent us comments, we sent them back.

7 Q. Were final agreements ever executed?

8 A. No, we never did execute final agreements.

9 Q. Why not?

10 A. Well, the last time I got the comments was in
11 the January-February period of 1998. At that point in
12 time, we had already fulfilled their cholestyramine
13 order under standard POs, and we were just waiting to
14 see if there was going to be additional activity
15 before -- before we incurred any additional legal
16 expenses as far as formalizing or finalizing the
17 agreement.

18 Q. I'm sorry, you said what happened under POs?

19 A. Well, we -- if you recall, one of the -- a
20 portion of the agreement was that they could buy our
21 cholestyramine for the United States at a -- and we
22 were sent either one or two POs requesting or
23 purchasing our cholestyramine, and like I said, that
24 was -- you know, what we did was we relied upon this --
25 our standard -- our standard terms and conditions, I

1 think.

2 I mean, I'm not trying to give a legal
3 conclusion here. I'm just saying that we basically
4 shipped the product as we would without a manufacturing
5 agreement.

6 Q. Sir, while we're on this document, USX 732,
7 under tab 3, I'd like to direct your attention to the
8 third page of this document. Do you have that page in
9 front of you?

10 A. Just for clarification, are you talking about
11 SP 1200203?

12 Q. Yes.

13 A. Okay.

14 Q. Thank you.

15 Do you see there's writing in the bottom margin
16 of that page?

17 A. Yes.

18 Q. Whose handwriting is that?

19 A. That's my handwriting.

20 Q. Can you please read into the record what it is
21 you've written there?

22 A. Yes. "'Sustained release microencapsulated
23 potassium chloride tablet'" shall mean a tablet made by
24 compressing individually coated potassium chloride
25 crystals within the coating containing ethylcellulose

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1 and at least one other ingredient."

2 Q. Sir, I'd like to direct your attention to the
3 document under tab 4.

4 A. Yes.

5 Q. Do you see that document, sir? What is that?

6 A. That's a letter that I sent to Mr. Kapur, the
7 president of Warrick Pharmaceuticals.

8 Q. Why did you send this letter?

9 A. Ian had -- it was at Ian Troup's request, Mr.
10 Troup's request.

11 Q. Did Mr. Troup say why he wanted you to send
12 this letter to Mr. Kapur?

13 A. I believe he had had a --

14 MS. BOKAT: Objection, hearsay.

15 MR. CURRAN: I'll withdraw that question, Your
16 Honor.

17 JUDGE CHAPPELL: Thank you.

18 BY MR. CURRAN:

19 Q. Mr. Kralovec, is that your signature on this
20 document?

21 A. Yes, it is.

22 Q. Sir, I want to direct your attention to the
23 first paragraph of this letter.

24 A. Yes.

25 Q. Why did you put that in your letter?

1 A. You mean, "Per your request to Ian Troup last
2 week"?

3 Q. That paragraph, yeah. I'm asking you why did
4 you write the words in that paragraph and put it in
5 this letter?

6 A. Well, the paragraph -- the entire letter was
7 intended to be a notification to -- my notification to
8 Warrick that we were discontinuing our Niacor-SR
9 product.

10 Q. Sir, there's reference in the final sentence of
11 that paragraph -- well, in fact, I'm going to read it.
12 It says:

13 "Upsher-Smith's NDA would have been two to
14 three years behind the launch of Niaspan."

15 What did you mean by that?

16 A. Well, in talking to Dr. Halvorsen, my
17 understanding was that additional clinical studies
18 would have been required to -- before we could have
19 effectively launched this product and that therefore we
20 felt we were going to be just behind the eight ball as
21 far as this product for too long a period of time.

22 Q. What's your understanding of what clinical
23 studies were required?

24 A. There were -- there were larger population
25 studies. You know, I don't recall the exact

1 configuration, but I just remember him basically saying
2 that to complete these studies and get them ready so we
3 could market this product, it was going to take a
4 couple years, two to three years.

5 Q. And what's your understanding as to why
6 additional clinical studies were required?

7 A. Well, Kos had received -- my understanding was
8 Kos had received additional indications that we were
9 surprised at, and so we needed to design these studies
10 so that we could have -- our product would be similar
11 to theirs from a labeling standpoint.

12 Q. Okay. Now, sir, in the sentence preceding the
13 one that I read -- in fact, I just note now, I didn't
14 read the full sentence there. Let me read that just to
15 clarify the record. The final sentence in that
16 paragraph states:

17 "In light of Niaspan's FDA approval,
18 Upsher-Smith's NDA would have been two to three years
19 behind the launch of Niaspan."

20 Have I read the whole sentence correctly that
21 time?

22 A. Yes, and it was that -- it was those
23 indications of the approval that -- that had us
24 concerned.

25 Q. Okay. Sir, the sentence immediately preceding

1 that one that I just read refers to an additional
2 multi-dose pharmacokinetic study. Is that what you
3 wrote in that sentence?

4 A. Yes.

5 Q. Okay. Why did you write that?

6 A. Well, I knew there was another PK study that
7 was -- that was -- I mean, I was informed that there
8 was another PK study that needed to be done besides, so
9 we had a PK study that needed to be done as well as
10 these additional studies.

11 Q. Sir, sitting here today, is it your
12 understanding that an additional multi-dose
13 pharmacokinetic study was required prior to the
14 submitting of Upsher's NDA?

15 A. No, it was a different kind of PK study. I
16 screwed up. I picked up probably the wrong term. I
17 understood that some kind of PK study was required, but
18 as far as it being multi-dose, I understand that that
19 was not correct.

20 Q. Sir, I want to refer you to the second
21 paragraph in this letter. Please, take a moment to
22 read it to yourself, and my question is, what did you
23 mean there?

24 A. (Document review.)

25 Q. I'll read it aloud, and you can follow, and

1 then I'll ask you about it.

2 A. All right.

3 Q. Okay. "Secondly, Kos Pharmaceuticals, Inc. has
4 been less successful with efforts to market Niaspan.
5 This is especially troubling to us in light of their
6 significant commitment to the sales and marketing
7 effort for this product. Their actions have reinforced
8 our decision not to invest any additional resources in
9 Niacor-SR."

10 Okay, did I read correctly what you wrote?

11 A. Yes.

12 Q. Okay. Why did you write that?

13 A. Well, if you recall, in their -- in their
14 information they were giving to the investment bankers,
15 they were saying they could do \$250 million. They were
16 doing substantially less than that, and this was a year
17 after they had launched the product. So, we were, you
18 know, very concerned about their capability, what they
19 were going to be able to do with it. The -- you know,
20 the really -- at that point in time, they had -- to the
21 best of my recollection, they had in excess of 100
22 salespeople, you know, pounding the doors of
23 physicians.

24 They were actively promoting this thing, and it
25 wasn't doing nearly as well, the concern being that

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1 basically they had -- you know, if they weren't able to
2 do well, if we were going to come out with a product,
3 it would be very difficult for us, because basically
4 once that product's been introduced and is -- you know,
5 it has a recognition, it's difficult to change that.
6 So, how would we get to \$100 million? Our concern was,
7 how would we get to \$100 million if they had a sales
8 force and were unable to do it?

9 Q. Sir, I want to direct your attention to the
10 third paragraph in this letter you wrote. I'll read it
11 and then again I'll ask you what you meant by it.

12 "The studies undertaken for the product have
13 been completed and these studies are available for
14 review at your convenience. Several of the studies are
15 not in final form, and are not suitable for submission
16 to a regulatory agency. Should you decide to proceed
17 to obtain approval in your agreed upon area, we will
18 address what resources would be necessary to get the
19 remaining studies into suitable form."

20 A. Yes.

21 Q. Did I read correctly what you wrote?

22 A. Yes.

23 Q. Why did you write that paragraph?

24 A. Well, when we made the decision to basically
25 cut our losses and not produce the product anymore --

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1 or excuse me, not continue on with those efforts, I
2 still felt we had an obligation to give Schering that
3 information with the hopes that they would take the --
4 at least take the product to Europe, to Europe, and
5 market that product. So, I was working with Dr.
6 Halvorsen and telling him we really need to get these
7 studies in final form so that we can, you know, give
8 that information to them so they can take it forward.

9 Q. Why did you want to get that information to
10 Schering?

11 A. Well, I felt that there was an obligation under
12 the agreement to -- to help them move through -- move
13 through that process of getting the product approved.

14 The other thing is I wanted that royalty stream
15 and I wanted those milestone payments.

16 Q. Which royalty stream and milestone payments are
17 you referring to?

18 A. The -- under the June 17th, 1997 agreement,
19 when they got -- when they got -- I've got to think
20 exactly how that worked, but basically there was -- we
21 had the ability to get money for them if they hit
22 certain milestones, and then once they were selling
23 that product, there was a royalty stream that would
24 come from the sales that they generated.

25 Q. I want to refer your attention to the next

1 paragraph in this letter. It reads:

2 "On a more pleasant note, Upsher-Smith has
3 re-initiated our work on pentoxifylline and expects to
4 submit our revised ANDA to the FDA by year-end. If you
5 wish to proceed with this project, the data should be
6 available for review in late December. Please advise
7 us how you wish to proceed."

8 Did I read that correctly?

9 A. Yes.

10 Q. Okay. What did you mean when you wrote that?

11 A. Well, again, this was another one of the
12 products that was under that agreement, and we wanted
13 them to go ahead with all the products that were in
14 that thing so that we would be able to -- you know, we
15 had an obligation as far as it related to that as well.
16 So, we were initiating our efforts and were wondering
17 what they wanted to do as far as initiating theirs.

18 Q. Okay. Now, sir, the general thrust of this
19 letter was to inform Mr. Kapur that Upsher was
20 terminating its research on Niacor-SR, correct?

21 A. That was -- that was the main purpose of the
22 letter.

23 Q. Were you involved in the decision at
24 Upsher-Smith to suspend all research on Niacor-SR?

25 A. Let me think if I was. I was -- I was aware of

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1 it when we made that decision. As far as that decision
2 being made directly by me, it was not.

3 Q. More broadly to continuing the research on
4 Niacor-SR, were you involved in the decision to stop
5 the development project on Niacor-SR?

6 A. It was definitely discussed among the senior
7 management group, and that decision was made to
8 discontinue that process. Again, it was -- you know,
9 it was like why would you throw good money after bad?
10 You know, we just felt that the product was not going
11 to do well in light of what Kos had done.

12 Q. Now, you had -- Upsher-Smith had invested a lot
13 of money in developing Niacor-SR, correct?

14 A. Absolutely. And it was very -- I mean, believe
15 me, this was a painful decision. It wasn't like we
16 said, well, take this away. As I mentioned, this
17 project -- if you think about it, this project was huge
18 for us. I mean, we had committed -- we had the entire
19 company committed, a significant amount of resources
20 for a significant period of time. So, this was not an
21 easy decision to make.

22 MR. CURRAN: Nothing further, Your Honor.

23 JUDGE CHAPPELL: Does Schering-Plough have any
24 questions?

25 MS. SHORES: No, Your Honor.

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1 JUDGE CHAPPELL: Cross?

2 MS. BOKAT: Yes, please.

3 CROSS EXAMINATION

4 BY MS. BOKAT:

5 Q. Good afternoon.

6 A. Good afternoon.

7 Q. You spoke this morning with Mr. Curran about
8 the \$60 million in the agreement that Schering was to
9 pay Upsher-Smith.

10 A. Yes.

11 Q. That was divided into three payments, correct?

12 A. Again, that -- my recollection was that there
13 was something being discussed on that, yes.

14 Q. Schering actually made the \$60 million in
15 payments to Upsher-Smith, did it not?

16 A. Yes, absolutely.

17 Q. Those payments were made in 1997, 1998 and '99?

18 A. To the best of my recollection, that's correct.

19 Q. Were distributions made in those years to
20 Upsher's shareholders --

21 A. Yes.

22 Q. -- in --

23 A. I'm sorry.

24 Q. -- in at least the amount of the payments?

25 A. I'm sorry, I interrupted you. Could you repeat

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1 the question?

2 Q. Sure.

3 In 1997, '98 and '99, weren't payments made to
4 shareholders of Upsher in at least the amounts of those
5 payments received from Schering?

6 A. Yes, they were, and there was a logical reason
7 for that. We're not --

8 Q. Thank you, you answered it.

9 A. Oh, okay.

10 Q. You didn't actually conduct any of the
11 negotiations on behalf of Upsher-Smith with Schering to
12 arrive at the settlement of the patent litigation, did
13 you?

14 A. I did not.

15 Q. So, sometimes people have talked about another
16 person from Upsher-Smith at the meeting they couldn't
17 remember, but it wasn't you.

18 A. It absolutely was not.

19 Q. Did Mr. Troup, though, when he was negotiating
20 with Schering come to you to discuss the structure of
21 the compensation under the license agreement?

22 A. Can you tell me what you mean by
23 "compensation".

24 Q. Payment by Schering to Upsher for the license
25 of Niacor-SR.

1 A. We talked about the -- we talked about the \$60
2 million if that's what you mean.

3 Q. Didn't he also ask you questions about what
4 compensation for licenses is common in the
5 pharmaceutical industry?

6 A. Yeah, and -- yes, he did. We --

7 Q. He wasn't familiar with pharmaceutical
8 licenses, was he?

9 A. No, that's absolutely not the case. He
10 absolutely was. He was involved in -- my understanding
11 was that when he was at Schwartz, he was involved with
12 those kinds of transactions as well. So, we were
13 talking about, you know, structures, but he definitely
14 was -- I mean, he was not ignorant of those types of
15 terms and conditions.

16 Q. He asked you whether it was common to see
17 up-front payments in pharmaceutical licenses, correct?

18 A. Well, we -- again, we talked about -- yes, we
19 talked about the structure of pharmaceutical licenses.

20 Q. Including up-front payments.

21 A. Yes.

22 Q. He asked you about those.

23 A. Yes.

24 Q. Did he ask you if it was common to see
25 milestone payments in pharmaceutical licenses?

1 A. Yes, he -- well, we talked about -- we talked
2 about milestone payments as well.

3 Q. He asked you about that, did he not?

4 A. We -- yes.

5 Q. And did he ask you whether it was common to see
6 royalty streams in licensing agreements in the
7 pharmaceutical industry?

8 A. Again, we talked about royalty streams as far
9 as the total package, yes.

10 Q. When Upsher-Smith began searching for a partner
11 to market Niacor-SR outside of the NAFTA countries, did
12 you do an evaluation of the value of such a license?

13 A. Did I personally you're saying?

14 Q. I should have been clearer, thank you.

15 Did Upsher-Smith do an evaluation?

16 A. I can't -- I don't know if they did or not.

17 Q. Did you personally do such an evaluation?

18 A. I -- no, I did not personally.

19 Q. When you were talking to Mr. Troup about
20 compensation in pharmaceutical licenses, did you give
21 him advice on how much compensation he should seek from
22 Schering?

23 A. By "compensation," do you mean the value or are
24 you -- the amount of payments that we would receive?

25 Q. Payments.

1 A. Again, I wasn't -- as far as the exact numbers,
2 no. I mean, we talked about different structures, is
3 it better to get money up front, looking at what is the
4 cash flow implications of that versus a milestone
5 payment versus a royalty stream, but he -- and looking
6 at it in total, but as far as the detailed terms and
7 conditions of it, no.

8 Q. You talked with Mr. Curran about an exchange of
9 draft agreements between Upsher-Smith and
10 Schering-Plough after June 17th.

11 A. Are you referring to the agreements in the
12 exhibits?

13 Q. Right.

14 A. Yes.

15 Q. And I think you said there were a couple -- you
16 actually looked at a couple of drafts that were
17 exchanged.

18 A. To the best of my recollection, there were --
19 there was at least one or two reiterations of that
20 process.

21 Q. And those agreements would have covered the
22 manufacturing by Upsher-Smith of the products licensed
23 to Schering-Plough, correct?

24 A. Yes, that's correct.

25 Q. And those agreements would have contained other

1 confidentiality provisions?

2 A. Yes.

3 Q. Provisions about development?

4 A. Yes, that's in our standard agreement.

5 Q. Quality assurance terms?

6 A. Yes.

7 Q. Would have also covered the royalties to be
8 paid by Schering to Upsher-Smith, correct?

9 A. There was --

10 Q. In fact, I think this morning you talked about
11 having corrected one of those provisions about
12 royalties.

13 A. Yes, you're right, the royalty stream as it
14 relates to the Niacor-SR was addressed in the
15 agreement.

16 Q. And the agreements also would have covered the
17 delivery of the licensed products from Upsher's
18 facilities to Schering, correct?

19 A. Yes, but again, we did ship product under POs,
20 so I mean it wasn't like you had to have this agreement
21 to basically ship product. We were treating them like
22 we would a lot of our other customers. We don't have
23 manufacturing agreements with every one of our
24 customers.

25 Q. The agreements would have covered patent

1 prosecution, correct?

2 A. I believe that it was in the agreement, yes.

3 Q. And covered related trademarks?

4 A. There was language as it relates to trademarks
5 as well.

6 Q. Those terms had not been included in the
7 agreement signed on June 17th, 1997, had they?

8 A. You know, I don't recall if they did or not.

9 Q. You don't recall them being in the June 17th
10 agreement.

11 A. I don't recall one way or another.

12 Q. You mentioned that you actually, even without
13 having the amended agreement executed, had shipped some
14 I think it was Prevalite to Schering-Plough?

15 A. Well, I believe it was cholestyramine. I don't
16 believe it was under the Prevalite name. It was a
17 generic version of that.

18 Q. Were those shipments made in late 1997, early
19 1998?

20 A. To the best of my recollection, we got the
21 orders in late -- you know, the fall of '97, and by the
22 time we got geared up and everything and shipped those
23 out, it actually was in early '98 that those shipments
24 actually went out.

25 Q. Were those the last shipments of cholestyramine

1 from Upsher to Schering-Plough?

2 A. In the -- I don't believe we shipped any
3 product after the spring of 1998.

4 Q. And Upsher never shipped any of the other
5 licensed products other than cholestyramine to
6 Schering, did you?

7 A. No, because we never received purchase orders
8 for them.

9 Q. So, cholestyramine was the only licensed
10 product that Schering ever ordered from Upsher-Smith?

11 A. Again, to the best of my recollection, that's
12 the only one that I'm aware of.

13 Q. Do you recall when the last draft of the
14 supplemental agreement was exchanged between Schering
15 and Upsher-Smith?

16 A. The last draft I received back from them, like
17 I said, that just got put on hold was in the -- to the
18 best of my recollection the December-January period of
19 time of 1998, you know, either December of 1997 or
20 January of 1998. That's the best of my recollection.

21 Q. After January of 1998, were there any more
22 communications from Schering about this supplemental
23 agreement?

24 A. No, it went quiet, but I wouldn't have expected
25 them to either until we were doing -- doing more work.

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1 Q. After January of 1998, were there any more
2 communications from Upsher to Schering about the
3 supplemental agreement?

4 A. Not that I recall at this time.

5 Q. You were describing for Mr. Curran the process
6 of purchasing potassium chloride, having it shipped to
7 IPC and then to Upsher.

8 A. Yes.

9 Q. Let me take you back through that. I think you
10 said the supplier that Upsher-Smith was going to use
11 for potassium chloride to go into the Klor Con M
12 products is a company called Reheis?

13 A. You're talking about the crystals themselves?

14 Q. Yes.

15 A. The crystals, yes, are made -- is Reheis, a
16 company out of Texas.

17 Q. Could you spell that for the court reporter,
18 please?

19 A. To the best of my recollection, it's R E H E I
20 S.

21 Q. So, was Upsher going to send purchasing orders
22 from Minnesota to Reheis in Texas for the potassium
23 salt?

24 A. Yes, we would have.

25 Q. And then was Reheis going to ship those

1 potassium salts from Texas to the IPC plant?

2 A. That's what's occurring now, yes, that's
3 correct.

4 Q. That IPC plant is in Kentucky, is it not?

5 A. Yes, I'm pretty sure, Lexington, Kentucky.

6 Q. After IPC coats the potassium chloride
7 crystals, does IPC then send those coated crystals to
8 an Upsher facility in Minnesota?

9 A. That's correct. They would be received at our
10 main manufacturing facility.

11 Q. Is it Upsher or IPC that pays Reheis for the
12 potassium salt?

13 A. To the best of my knowledge, I believe we pay
14 Reheis directly.

15 Q. Are funds sent from Upsher's bank account at a
16 bank in Minnesota?

17 A. Our main banking relationship is in Minnesota,
18 yes.

19 Q. Whence are those payments sent to Reheis?

20 A. Well, it would be based upon their purchase
21 orders, so if you're asking me when, I guess it
22 would -- the terms and conditions are on the POs, I
23 believe.

24 Q. I think I got you confused with my tortured
25 English grammar.

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1 When the money is sent from Upsher's bank
2 account in Minnesota to Reheis, where is that money
3 going?

4 A. It's going to Texas. Oh, well, I shouldn't say
5 that. I really don't know where their bank is. I
6 really don't know for sure.

7 Q. Is their bank outside Minnesota?

8 A. I really don't even know.

9 Q. I think you said you are also currently in
10 charge of distribution. Is that right?

11 A. That recently changed. I'm not anymore as of
12 October. We had a restructuring, so actually
13 distribution -- the distribution is under Phil Dritsas.

14 Q. Is that October of 2001 that that change in
15 your responsibilities occurred?

16 A. Yes, that's correct.

17 Q. Upsher-Smith was shipping Klor Con M20 in
18 September 2001, correct?

19 A. They definitely were.

20 Q. And you were in charge of distribution at that
21 time?

22 A. Yes, I was.

23 Q. Was Upsher shipping Klor Con M20 from
24 Minnesota?

25 A. Yes.

1 Q. Where did you ship it?

2 A. Well, it would have been to all the major
3 wholesalers and chain distribution centers throughout
4 the United States.

5 Q. So, a large portion of that Klor Con M20 was
6 being shipped outside Minnesota, correct?

7 A. That would be correct.

8 Q. Do you know what percentage was shipped out of
9 the state?

10 A. Boy, I would just be guessing.

11 Q. Do you have an educated guess?

12 A. You know, I wouldn't even want to speculate.
13 It would be -- put it this way: It would be a
14 significant portion of it, but if you -- to ask me if
15 it was, you know, 70, 80, 90 percent, I don't know. I
16 can definitely say that I believe that it would be in
17 excess of 70 percent, but we'd have to check the
18 numbers to confirm that.

19 Q. I assume that Upsher is paid for Klor Con M20
20 by its customers. Am I right?

21 A. Hopefully, yes.

22 Q. Are those payments made to your bank in
23 Minnesota?

24 A. Yes, that's correct.

25 Q. So, some of those payments are coming from

1 outside Minnesota into that bank in Minnesota, correct?

2 A. Yes, that would be absolutely correct.

3 Q. You were talking earlier today about bonuses to
4 Upsher-Smith employees. In 1997, did the employees
5 receive their bonuses?

6 A. Yes, we did. Well, let me clarify that. The
7 bonuses that would have been earned in 1997 were paid
8 in 1998. No, the bonus that would have been earned in
9 1996 -- there wasn't a bonus or it was a very minimal
10 bonus for the bonus that would have been paid in 1997
11 for the 1996 period of time.

12 Q. Thank you for clarifying that. What I really
13 wanted to ask was the bonus for work in 1997, and you
14 say that was paid in 1998?

15 A. There was a bonus paid in 1998, that's correct.

16 MS. BOKAT: Your Honor, may I approach the
17 witness, please?

18 JUDGE CHAPPELL: Yes.

19 BY MS. BOKAT:

20 Q. Mr. Kralovec, I hand you a document that has
21 been marked USX 132.

22 A. Okay.

23 MS. BOKAT: We're going to have to use the ELMO
24 for this one, Your Honor, so would you like a paper
25 copy?

1 JUDGE CHAPPELL: Not if it's on the ELMO,
2 thanks.

3 THE WITNESS: Yes.

4 BY MS. BOKAT:

5 Q. USX 132 is the contract between Upsher-Smith
6 and Moreton, correct?

7 A. Yes.

8 Q. Was it Vickie O'Neill who negotiated that
9 contract on behalf of Upsher-Smith?

10 A. Vickie had the direct contact with David Pettit
11 on this agreement, yes.

12 Q. But before this agreement was entered into, you
13 discussed with Ms. O'Neill the payments to Moreton,
14 correct?

15 A. The remuneration portion of this was -- I
16 addressed with Ms. O'Neill.

17 Q. During the discussions between Upsher-Smith and
18 Moreton leading to this contract, was there a proposal
19 that there be a flat fee of 2.5 percent paid from
20 Upsher to Moreton, that is, 2.5 percent of any money
21 that came in to Upsher through the license?

22 A. To the best of my recollection, the initial
23 proposal that came to us from him had such a fee, yes.

24 Q. And you personally felt that that would be too
25 expensive, did you not?

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1 A. Yes, particularly as we got into the sums of
2 money that I thought would be appropriate to receive
3 for this kind of license.

4 Q. So, Upsher negotiated with Moreton paying a fee
5 that was a percentage of the up-front and milestone
6 payments paid for a license of Niacor-SR, correct?

7 A. You know, I -- I'd have to look. That's --
8 what was negotiated here was -- was the -- was the
9 structure that included up-front and milestone
10 payments. The -- I don't recall if Pettit's original
11 agreement on the 2 and a half percent, what that
12 specifically was asking for, but I believe it was
13 basically the large lump sums of money.

14 Q. Yeah, I was trying to focus now on the actual
15 contract between Upsher and Moreton.

16 A. Yes.

17 Q. The success fee was to be based on up-front and
18 milestone payments, correct?

19 A. Or other large capital lump sum payments.

20 Q. But that would exclude royalty payments made
21 under the license, right?

22 A. That was my understanding at the time.

23 Q. And this is a declining payment, correct?

24 A. Absolutely.

25 Q. In other words, Moreton would earn 5 percent of

1 the first million dollars paid to Upsher-Smith but only
2 4 percent of payments up to \$2 million.

3 A. Well, actually, the structure is that if the
4 payments -- if a transaction were to occur where the
5 payment were up to \$1 million, he would receive 5
6 percent. If the payment of the agreement was for \$2
7 million or let's say \$1,999,000, he wouldn't receive 5
8 percent on the first million and 4 percent on the
9 second. He would receive 4 percent on the entire
10 amount.

11 Q. And if the payment was up to \$3 million,
12 Moreton would get 3 percent of the payment, right?

13 A. Right. So, it doesn't step. It's just 3
14 percent of the entire transaction.

15 Q. And that tops out at 1 percent of payments in
16 excess of \$5 million.

17 A. Well, actually, I believe it would be in excess
18 of \$4 million.

19 Q. You're right, because up to \$5 million, they
20 get 1 percent, and they get that same 1 percent for
21 everything over \$5 million.

22 A. Right, that's correct.

23 Q. So, you didn't try to negotiate a lower
24 percentage than 1 percent for the payments over \$5
25 million, correct?

1 A. I'm sorry, say that again.

2 Q. You didn't try to negotiate a lower fee than 1
3 percent for the payments over \$5 million.

4 A. No, I didn't.

5 Q. Upsher never --

6 A. Well, let me clarify. I didn't try to
7 negotiate anything. Vickie O'Neill is the one that
8 negotiated the terms and conditions of this agreement.

9 Q. And you didn't suggest to Ms. O'Neill that she
10 negotiate less than 1 percent for amounts over \$5
11 million, did you?

12 A. I did not. I felt 1 percent was a reasonable
13 fee.

14 Q. Upsher never actually paid Moreton's success
15 fee, did you?

16 A. No, because they didn't succeed.

17 Q. You testified earlier in the day about --

18 A. Are we finished with this?

19 Q. Yes, and I'll take it back, that way you're not
20 buried in paper here.

21 A. Okay.

22 Q. Thank you.

23 You testified earlier in the day about a
24 cross-license agreement between Kos and Upsher-Smith.

25 A. Yes.

1 Q. That concerned patents that related to your
2 respective sustained release niacin products, correct?

3 A. Well, again, as you mentioned, I'm not a
4 lawyer, but my understanding as a layperson is that one
5 of the patents covers niacin and other products, and
6 one of the patents specifically is related to niacin.

7 Q. Under the agreement, Upsher licensed -- it was
8 two patents to Kos?

9 A. Yes, that's correct. To the best of my
10 recollection, it was what we called the Evenstad and
11 the O'Neill patents.

12 Q. And Kos licensed at least one patent to Upsher,
13 did it not?

14 A. Well, there was this patent pending, so I
15 believe that we got those rights should the patent be
16 issued. That's my recollection of what was going on.
17 There was that whole -- that's why that whole patent
18 interference thing was happening in the first place,
19 was because the patent had not actually been issued.
20 So, my understanding -- my -- the best of my
21 recollection, if their patent issued, then we got
22 those -- those rights.

23 Q. And under the license agreement, Kos had the
24 right to sublicense the two Upsher patents, the O'Neill
25 and Evenstad patents, correct?

1 A. You know, I would have to look at that
2 agreement to be sure.

3 Q. You don't recall?

4 A. I'm not positive on that.

5 Q. Do you recall whether Upsher-Smith had the
6 right to sublicense Kos' patent if the patent issued?

7 A. That one I'm pretty sure we were not allowed to
8 do. There was something to do with that where there
9 was a restriction from that standpoint. I remember
10 them saying that they wanted -- that they had gotten
11 more rights as it related to their ability to -- our
12 ability to use their patent than they got relative to
13 ours.

14 Q. So, it's your recollection that Upsher did not
15 have the right to sublicense the Kos patent if it
16 issued?

17 A. I'm -- again, to the best of my recollection, I
18 believe that's the case, but I'm not positive.

19 Q. I want to make sure I understand something you
20 said earlier in the day.

21 Under the cross-license, there were up-front
22 and royalty payments of \$3 million. Was that from Kos
23 to Upsher?

24 A. That's correct. To the best of my
25 recollection, we got a million dollars upon signing,

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1 another million dollars at the end of 1997 and an
2 additional million dollars in the early spring of 1998,
3 and then as they sold the product, we received a
4 royalty besides.

5 Q. So, the additional \$2.5 million in payments
6 were in the form of royalties from Kos to Upsher. Is
7 that right?

8 A. That's -- to the best of my recollection,
9 that's the case.

10 Q. I believe you testified earlier that in terms
11 of safety, Upsher's Niacor and -- or Niacor-SR and Kos'
12 Niaspan were virtually identical?

13 A. No, I wasn't trying to imply that. I wasn't
14 saying -- I'm not trying to say from a -- what I was
15 saying is my perception -- our perception was that we
16 had very similar type products. As far as the safety
17 and efficacy profile, I wasn't trying to espouse a
18 legal or, excuse me, a scientific opinion on it.

19 Q. Well, taking a nonscientific interpretation, if
20 that's what it was, on the safety and efficacy, were
21 you saying that the two products were very similar in
22 terms of safety and efficacy?

23 A. No, what I was saying is that we had very
24 similar sustained release niacin products. I don't --
25 I don't know that I ever knew what their safety and

1 efficacy profiles were.

2 Q. All right. Isn't it true -- I'm sorry, go
3 ahead.

4 A. Yes.

5 Q. Isn't it true that Upsher usually attempts to
6 launch a product as soon as it has FDA approval if
7 there isn't patent litigation ongoing?

8 A. Yes.

9 Q. As of May -- actually, before I get into that.
10 Your Honor, I can proceed if you want. This is
11 a logical breaking time. If you want to take a lunch
12 break, just let me know what the Court's pleasure is.

13 JUDGE CHAPPELL: How much time do you have
14 remaining on your cross, ballpark?

15 MS. BOKAT: I would guess about half an hour.

16 JUDGE CHAPPELL: Let's press on until about a
17 quarter after.

18 MS. BOKAT: Okay.

19 JUDGE CHAPPELL: Thank you.

20 BY MS. BOKAT:

21 Q. As of May 1997, Upsher was planning to launch
22 its 20 milliequivalent potassium chloride tablet in
23 late 1997 or early 1998, was it not?

24 A. We were making plans -- we were looking at the
25 possibility of launching it during that period of time.

1 Q. Upsher was making sure in that period of time
2 that they had the equipment in place to launch Klor Con
3 M20, correct?

4 A. Well, again, it depends -- we didn't have a
5 definitive forecast, so depending on how much we were
6 going to manufacture would have defined that, would
7 have defined that answer.

8 Q. But at that time, Upsher was trying to make
9 sure it had equipment in place for the launch, correct?

10 A. The one thing that I was aware that
11 specifically I knew we had to have for that launch was
12 a press. As far as the other pieces of equipment, that
13 would have really depended upon what we finally came to
14 a conclusion on as far as the need for -- our demand
15 was going to be for a launch.

16 Q. So, in that time period, the only thing you
17 knew of you needed in addition was a tablet press?

18 A. A press.

19 Q. But it's not a tablet press?

20 A. It is a tablet press.

21 Q. Upsher had identified a source for that tablet
22 press, had it not?

23 A. Well, traditionally we have used Kikisui, which
24 is a Japanese press that we've tended to use in the
25 past, and I mean that would really be the call of

1 manufacturing, but my -- I would have speculated at the
2 time that we would have used Kikisui because we've used
3 them in the past, and it's -- you know, you don't -- if
4 you have the same kind of press, it's much easier to
5 manufacture your product, you know, consistent type of
6 presses.

7 Q. Could you spell Kikisui for the court reporter,
8 please?

9 A. K I K I S U I, I think it is.

10 Q. Thank you. I'm certainly not going to correct
11 you.

12 As of the spring of 1997, Upsher certainly
13 expected to have a tablet press in place by the fall of
14 1997, did it not?

15 A. The lead times aren't real long on that, so I
16 mean, did we ever place an order? No, we never placed
17 an order for a tablet press.

18 Q. No, but did you expect it to have it in place
19 by the fall of 1997?

20 A. The lead times weren't real long, so if we had
21 ordered one in the springtime, I think by the fall of
22 that year, yes, we probably could have had one. I
23 think generally speaking, yes, we could have had one
24 within about a six-month period of time.

25 MS. BOKAT: Your Honor, may I approach the

1 witness, please?

2 JUDGE CHAPPELL: Yes, you may.

3 BY MS. BOKAT:

4 Q. Mr. Kralovec, what I handed you is a transcript
5 of an investigational hearing you gave. Do you recall
6 giving an investigational hearing here in Washington in
7 May of 2000?

8 A. No. I believe I gave it in Minneapolis.

9 Q. Right, you were fortunate enough to give a
10 deposition in Minneapolis, but do you recall even
11 earlier than that coming to Washington --

12 A. No, I don't think I ever came to Washington
13 for --

14 Q. You're right, you're right, they were both in
15 Minneapolis.

16 A. Yes.

17 Q. Thank you. All right, let me try a new
18 question.

19 Do you recall giving an investigational hearing
20 in May of 2000 in Minneapolis?

21 A. Very well.

22 Q. Would you look at page 30 of the transcript,
23 please, beginning at line 3. Were you asked and did
24 you answer:

25 "QUESTION: You mentioned that Upsher-Smith

1 would have to have some additional equipment in house
2 for the launch of the 20 mEq product.

3 "ANSWER: Right."

4 I'm reading your testimony accurately so far?

5 A. Yes, those are the words.

6 Q. The next question:

7 "QUESTION: What equipment was that?

8 "ANSWER: Well, the most important we wanted
9 to -- the most important piece of equipment that we
10 needed was the tablet press, a new tablet press."

11 Am I reading accurately so far?

12 A. Yes.

13 Q. Next question:

14 "QUESTION: When did Upsher-Smith anticipate
15 they would have that in place?

16 "ANSWER: We would have -- it would have been
17 put in place about in the fall of 1997," and then the
18 answer continues on.

19 Was I correct as far as I read?

20 A. Yes.

21 Q. In the period of May 1997, Upsher-Smith was
22 making sure that IPC had the capability to support your
23 launch of Klor Con M20, were you not?

24 A. Could you repeat the question? I'm sorry.

25 MS. BOKAT: Would it be all right if the court

1 reporter read it back, Your Honor?

2 JUDGE CHAPPELL: Yes, if it's all right with
3 her.

4 (The record was read as follows:)

5 "QUESTION: In the period of May 1997,
6 Upsher-Smith was making sure that IPC had the
7 capability to support your launch of Klor Con M20, were
8 you not?"

9 THE WITNESS: Well, let me answer it this way:
10 We knew we needed IPC to manufacture the product, and
11 we were looking at what the capabilities were.

12 BY MS. BOKAT:

13 Q. In the spring of 1997, Upsher decided to go
14 ahead with some validation batches for Klor Con M20,
15 did you not?

16 A. No, we did not.

17 MS. BOKAT: Your Honor, may I approach the
18 witness, please?

19 JUDGE CHAPPELL: Yes.

20 BY MS. BOKAT:

21 Q. Mr. Kralovec, I handed you a transcript of your
22 deposition. Do you recall being deposed in Minneapolis
23 in September 2001?

24 A. Yes, I do.

25 Q. Would you look, please, at page 33 of this

1 transcript.

2 A. Okay. Yes.

3 Q. Beginning at line 2, were you not asked and did
4 you not answer:

5 "QUESTION: Was it in early 1997?

6 "ANSWER: It -- it was during -- it was during
7 the spring of '97 that we'd made a decision to go ahead
8 and at least do some -- do some validation work."

9 Was that your testimony?

10 A. Yes, but that validation -- to the best of my
11 knowledge, that validation work was never done.

12 Q. But a decision was made at some point to go
13 ahead with the validation work.

14 A. And -- well, a decision was made that I
15 cancelled.

16 Q. That you cancelled later?

17 A. Yes.

18 Q. Those validation batches were planned for June
19 of 1997, were they not?

20 A. Yes, that was my understanding.

21 Q. The validation batches would be produced at IPC
22 and at Upsher-Smith?

23 A. Yes, you would -- well, obviously what you've
24 got to do is you've got to coat the tablets -- or
25 excuse me, coat the salt at IPC, bring it up for

1 additional mixing and compression.

2 Q. And that was planned to be done in June 1997?

3 A. Well, by the time it would get up to us and get
4 compressed, I mean, the lead time now is right around
5 four to five weeks, so it probably would have been
6 going into July had we gone forward with that before we
7 even would have had the product compressed in
8 Minneapolis.

9 Q. But the coating was going to occur in June at
10 IPC, June of '97?

11 A. The -- the proposed plan was to do some
12 validation -- do the validation -- do validation work
13 in June of '97.

14 Q. Upsher tries to schedule its validation batches
15 not much more than six months before the commercial
16 launch of the product, correct?

17 A. Generally speaking.

18 Q. And that's because Upsher wants to use those
19 validation batches as part of the commercial launch.
20 Is that right?

21 A. Yes, but there are times that if it doesn't
22 work out, we end up throwing the stuff away. So, you
23 know, ideally, under -- you know, ideally we would like
24 to use them.

25 Q. So, you prefer not to have to throw that

1 material away.

2 A. But at the same time, we have in the past.

3 Q. After Upsher-Smith and Schering-Plough entered
4 into the June 17th, 1997 settlement agreement, Upsher
5 lowered the priority of Klor Con M20, did it not?

6 A. After it -- we -- because we had a date certain
7 which was so far out, yes, we -- some of the activities
8 slowed down.

9 Q. And some people were re-assigned to other
10 projects. Is that right?

11 A. Sure.

12 Q. Was it in the third quarter of 1999 that
13 intense efforts toward the launch of Klor Con M20 were
14 begun?

15 A. Well, the planning process started much earlier
16 than that. I mean, we were looking at -- we were
17 looking at capacities at IPC as well as Upsher-Smith,
18 to the best of my recollection, starting even in the
19 spring but definitely going into the summer of 1999
20 already.

21 Q. But that wasn't done in the second half of '97
22 or 1998.

23 A. Well, no, because we knew that we had a date
24 certain, that being September 1st of 2001.

25 Q. In hindsight, you've expressed some concerns

1 about IPC's capacity to produce the coated crystals for
2 Klor Con M20, correct?

3 A. Their capacity, yes.

4 Q. But you didn't have those concerns in early
5 1997, did you?

6 A. Well, again, the concern -- the only concern I
7 had was I didn't -- until I knew what we were going to
8 produce, I couldn't have a concern.

9 Q. Subsequent to 1997, Upsher anticipated a larger
10 launch for Klor Con M20 than you did back in '97,
11 correct?

12 A. I can't answer that, because I don't think we
13 ever -- I can tell you as a senior management group, we
14 never authorized a launch plan that detailed what we
15 were going to produce for that launch in the 1997
16 period of time.

17 Q. Since 1997, the market for 20 mEq potassium
18 chloride tablets has grown, has it not?

19 A. You know what, you'd have to ask marketing on
20 that.

21 Q. Okay, so we will go with what Mr. Dritsas told
22 me on that?

23 A. Okay.

24 Q. As of January 1999, Upsher understood that you
25 would have the 180-day exclusivity period for Klor Con

1 M20. Is that right?

2 A. As of what date?

3 Q. January 1999.

4 A. You know, I can't tell you if it was that date.
5 I know prior to the launch we were -- we were told that
6 we would have the exclusivity, but I don't recall the
7 specific date of when we were informed of that.

8 JUDGE CHAPPELL: Ms. Bokat, is this a good
9 breaking point?

10 MS. BOKAT: Yes, it is, Your Honor.

11 JUDGE CHAPPELL: Okay, let's adjourn for lunch
12 until 2:15.

13 (Whereupon, at 1:15 p.m., a lunch recess was
14 taken.)

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1 AFTERNOON SESSION

2 (2:15 p.m.)

3 JUDGE CHAPPELL: Ms. Bokat, whenever you're
4 ready.

5 MS. BOKAT: Thank you, Your Honor.

6 BY MS. BOKAT:

7 Q. Mr. Kralovec, could we turn back, please, to
8 your investigational hearing transcript, if you still
9 have it? That's the May 2000 transcript.

10 A. Yes.

11 Q. Would you look with me at page 30, please.

12 A. Sure. Yes.

13 Q. Before the lunch break, we were actually
14 reading a portion of that when we were talking about
15 the tablet press for Klor Con M20 that Upsher would
16 need.

17 A. Yes.

18 Q. And I didn't read the entire answer. I'd like
19 to do that now with Ms. Hertzman's assistance.

20 Beginning at line 11:

21 "QUESTION: When did Upsher-Smith anticipate
22 they would have that in place?" Which is a reference
23 back to the tablet press.

24 "ANSWER: We would have -- it would have been
25 put in place about in the fall of '97. We had tablet

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1 presses. I don't want to imply that we didn't have
2 tablet presses. We had the capability of manufacturing
3 this product, but we wanted to expand our capabilities,
4 so it wasn't like we couldn't manufacture it, but this
5 would have helped us enhance our capabilities.

6 "QUESTION: Was that a question of additional
7 capacity?

8 "ANSWER: It was to smooth capacity, so we had
9 the capability of manufacturing, but again, it was --
10 this would have been a higher -- a press with more
11 capacity."

12 So, as of the spring of 1997, Upsher-Smith had
13 the capability of manufacturing Klor Con M20, did it
14 not?

15 A. Well, from -- just from the standpoint that we
16 had approval, obviously we had the capability of
17 manufacturing some M20 tablets.

18 Q. So, you could have gone to market with some M20
19 tablets. Is that right?

20 A. Would have and could have were two different
21 things. We could have; we would not have to the best
22 of my -- to my belief.

23 Q. But you could have?

24 A. It's a possibility. The other thing you have
25 to consider, though, is --

1 Q. Thank you, you answered that.

2 You mentioned earlier in the day that you
3 personally had made some visits to IPC.

4 A. That's correct.

5 Q. Was that in connection with Upsher-Smith
6 lending money to IPC?

7 A. Well, it was that and making sure that they
8 were on track for getting the equipment so they would
9 have the capacity we needed.

10 Q. When did you make those trips to IPC?

11 A. To the best of my recollection, I was there --
12 well, to IPC itself, I went there in the fall of 2000,
13 again in the summer of 2000, then I believe again in
14 the fall -- excuse me, the summer of 2001 and the fall
15 of 2001. The visits -- to the best of my recollection,
16 those are the visits I made to IPC itself.

17 Q. So, all those visits occurred after the time in
18 1999 when Upsher began gearing up for the September
19 2001 launch of Klor Con M20.

20 A. Yeah, then a -- actually then I'll take that
21 back. There was definitely a visit that occurred right
22 after that when there was an engineering study that was
23 proposed, and we were negotiating on the terms and
24 conditions of the agreement, which was in the -- that
25 was in the '99 period of time as well. So, I would

1 have gone in the fall of -- fall of that year as well
2 to -- basically where we laid out the basic terms and
3 conditions for the manufacturing agreement and the
4 subsequent repayment of the loan.

5 Q. So, that was fall of '99?

6 A. Fall of '99.

7 Q. Between the date of the Schering-Plough
8 agreement in June of 1997 and the fall of 1999 when you
9 were gearing up for the launch of Klor Con M20, Upsher
10 introduced some new products, did it not?

11 A. Well, the biggest one I remember that was
12 introduced during that period of time was Pacerone.

13 Q. And that's turned out to be a large product for
14 Upsher-Smith, has it not?

15 A. It's been a great product for us.

16 Q. Do you manufacture Pacerone at your facilities?

17 A. We compress the tablets there. I don't know if
18 I recall whether all of the processes are manufactured
19 there or not.

20 Q. Do you also bottle Pacerone in your facilities?

21 A. Yes.

22 Q. Do you mix some ingredients in your facilities
23 before pressing the tablets?

24 A. Yes.

25 Q. So, did Pacerone take up some of Upsher-Smith's

1 manufacturing capacity?

2 A. Yes.

3 Q. So, by the time in 1999 when you began gearing
4 up for production of Klor Con M20, Pacerone had
5 absorbed some of Upsher's facilities, correct?

6 A. Yes, but I can tell you that when we started
7 looking at the M20, just because of the size -- the M10
8 and the M20, just because of the size of the tablet and
9 the number of tablets we needed, the 91 million tablets
10 and the capacity on an ongoing basis to do that, that
11 was nearly 50 percent of our total capacity of that
12 facility. So, if you can imagine, what I'm saying is
13 even if you backed out the Pacerone, you know, I'd have
14 to punch the numbers, but my perception would be that
15 we would have had an extremely difficult time, even if
16 we were to exclude any other products that we
17 introduced before that, to manufacture the M20 at the
18 levels where we launched the product.

19 Q. But if it weren't for Pacerone, you wouldn't
20 have had to make as many additions to the facility,
21 right?

22 A. Well, when we made the addition, we made the
23 addition -- what we did was, we didn't make the
24 addition just to meet the M20 needs. We built out that
25 facility as big as we possibly could. There's

1 limitations from a city standpoint on how much -- how
2 big a facility you can build relative to the parking
3 space and the green space around it, and basically what
4 we did was we said, what's the maximum -- because we
5 have to make an additional expansion, let's build it
6 out as big as we possibly can and have additional
7 capacity going into the future beyond the M10 and M20
8 products.

9 Q. Mr. Kralovec, do you still have the white
10 binder that Mr. Curran gave you this morning?

11 A. I do.

12 Q. We're going to try and pull that one up on the
13 screen. That's CX 1111. Again, this is a letter from
14 you to Mr. Kapur at Warrick?

15 A. That's correct.

16 Q. Dated October 6th, 1998, right?

17 A. Let me get my glasses. That date again?

18 Q. October 6th, 1998?

19 A. Yes.

20 Q. When you were talking with Mr. Curran this
21 morning, you mentioned that you had made an error in
22 one of the paragraphs.

23 A. That's correct.

24 Q. Was it the paragraph about the studies that had
25 yet to be done?

1 A. Yes.

2 Q. Did you ever send a correction letter to
3 Warrick or Schering?

4 A. You know, I didn't.

5 Q. Did you ever communicate the correction to
6 anyone at Schering or Warrick?

7 A. You know, I actually, after I wrote this
8 letter, I probably had not looked at it for a
9 significant period of time, so I -- no, I didn't do
10 anything like that.

11 Q. This was the first time you notified Schering
12 that Upsher had suspended the research on Niacor-SR.
13 Is that right?

14 A. Personally?

15 Q. Yes.

16 A. This is the first time I personally had.

17 MS. BOKAT: Your Honor, could I have just a
18 minute, please?

19 JUDGE CHAPPELL: Yes, you may.

20 (Counsel conferring.)

21 MS. BOKAT: Thank you, Your Honor. That
22 concludes my cross examination of Mr. Kralovec.

23 JUDGE CHAPPELL: Redirect?

24 MR. CURRAN: Yes, Your Honor.

25 JUDGE CHAPPELL: Go ahead.

1 REDIRECT EXAMINATION

2 BY MR. CURRAN:

3 Q. Mr. Kralovec, I'm going to ask you a number of
4 questions dealing with topics addressed in Ms. Bokat's
5 questioning.

6 First, do you recall her questions about the
7 three payments totaling \$60 million that Upsher
8 received from Schering-Plough?

9 A. For the licensing of those products?

10 Q. That's right.

11 A. Yes.

12 Q. Okay. Sir, I want to be clear here, did
13 Upsher-Smith receive a single lump sum \$60 million in
14 June of '97?

15 A. We did not.

16 Q. Okay. Did you receive instead three payments?

17 A. There were three what I would consider up-front
18 payments, because it was just over time. The -- there
19 were three payments, of \$28 million -- to the best of
20 my recollection, \$28 million within a few weeks of
21 signing the agreement, after we had board approval by
22 the Schering board. Then there was \$20 million that
23 was received on the first anniversary of the agreement,
24 and \$12 million on the second anniversary of that
25 agreement.

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1 Q. Okay. Was the value of those three payments
2 worth \$60 million as of June 17th, 1997?

3 A. Well, the -- I mean, if you took the net
4 present value of those payments, probably -- depending
5 on the discount rate, probably it could be discounted
6 down to maybe \$55, \$54 million.

7 Q. What does "net present value" mean?

8 A. Well, you can take -- a dollar in the future is
9 worth less to you than it is now, because you can
10 invest those dollars. So, what you do is you take a
11 discount rate or a rate that you say would be
12 reasonable for a return that you'd expect on that
13 investment, and you take it back and discount it back
14 to the present date.

15 Q. Sir, do you remember when Ms. Bokat asked you a
16 question or two dealing with shareholder distributions?

17 A. Yes.

18 Q. Okay. Sir, my question to you, who financed
19 the R&D for the Niacor project?

20 A. The shareholders.

21 Q. How did they do that?

22 A. Well, out of -- rather than taking
23 distributions in the past, they basically decided to
24 return that money to the company so that we could make
25 those investments.

1 Q. Sir, what's the type of corporate entity that
2 Upsher-Smith is?

3 A. We're an S Corp, which means that from a legal
4 standpoint -- and again, I'm not talking as a lawyer --
5 but from a legal standpoint, my understanding is we're
6 treated as a corporation, but from a tax standpoint,
7 we're treated as a partnership. So, therefore, the net
8 effect of that is the income flows through on the
9 individual shareholders' income statements or I should
10 say returns.

11 Q. Returns, okay. An S Corporation is a tax law
12 device, correct?

13 A. That's correct.

14 Q. Sir, in one of your questions or answers -- in
15 one of the questions or answers in the cross
16 examination, you referred to Mr. Troup's experience at
17 Schwartz Pharma?

18 A. Yes.

19 Q. Were you referring to prior work history of Ian
20 Troup?

21 A. That's correct.

22 Q. And is it prior to when he joined Upsher-Smith?

23 A. Prior to 1995, yes.

24 Q. Where did Mr. Troup work with Schwartz Pharma?

25 A. You would have to ask Ian for sure, but my

1 understanding is he worked in the UK, in Germany as
2 well as in the United States for Schwartz Pharma.

3 Q. Okay.

4 A. To the best of my recollection.

5 Q. Sir, Ms. Bokat also asked you some questions
6 dealing with the Kos cross-licensing agreement,
7 correct?

8 A. Yes.

9 Q. Sir, I want the record to be clear here. Under
10 that cross-licensing agreement, as you understand it,
11 was Upsher-Smith free to license Niacor-SR outside the
12 United States?

13 A. Yes, absolutely.

14 Q. And that was something specifically negotiated
15 with Kos?

16 A. That's correct.

17 Q. Sir, finally, after the lunch break, Ms. Bokat
18 asked you questions about Upsher-Smith's capacity to
19 manufacture in 1997.

20 A. Yes.

21 Q. And I think you may have been cut off, but you
22 were saying that Upsher-Smith could have manufactured
23 Klor Con M20 but would not have?

24 A. Yes.

25 Q. Can you explain that answer?

1 A. Well, again, I don't -- based upon the launch
2 that we had now, we did not have the capacity/, I
3 believe even excluding the new products, my
4 perception -- my -- based upon the information I've
5 seen, we would not have had the capabilities of
6 manufacturing all the product we needed to have a
7 successful launch, and rather than jeopardizing our
8 reputation in the industry, which is basically our key
9 thing that we add a value is our ability to deliver the
10 product to our customers, we would not have taken that
11 risk at that point in time.

12 MR. CURRAN: Nothing further, Your Honor.

13 JUDGE CHAPPELL: Recross?

14 MS. BOKAT: Yes, please. Should I defer to
15 Schering if they have any redirect before I --

16 MR. NIELDS: We have none, Your Honor.

17 JUDGE CHAPPELL: Thank you.

18 RE CROSS EXAMINATION

19 BY MS. BOKAT:

20 Q. Mr. Kralovec, you just mentioned that the third
21 of those payments from Schering was made on the second
22 anniversary of the agreement, right?

23 A. To the best of my recollection, it was the --
24 yeah, so it would have been in -- to the best of my
25 recollection, it was in June of 1999.

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1 Q. So, that was after you sent the letter to Mr.
2 Kapur notifying him that Upsher had stopped work on
3 Niacor-SR.

4 A. That's correct.

5 MS. BOKAT: Nothing further, Your Honor.

6 MR. CURRAN: May I, Your Honor, limited to the
7 recross?

8 JUDGE CHAPPELL: Okay.

9 FURTHER REDIRECT EXAMINATION

10 BY MR. CURRAN:

11 Q. Mr. Kralovec, do you still have the binder in
12 front of you?

13 A. Yes, I do.

14 Q. Can you look to tab 4, please?

15 A. Yes.

16 Q. This is the letter Ms. Bokat just referred to,
17 correct?

18 A. I believe that's what she was talking about.

19 Q. Okay. Please, put your glasses on.

20 That's the letter she was referring to,
21 correct?

22 A. My impression was that she was referring to
23 this letter.

24 Q. Sir, in the third paragraph of that letter?

25 A. Yes.

1 Q. That's where you're indicating that the studies
2 that Upsher-Smith performed are available for
3 Schering-Plough?

4 A. Yes, I specifically asked Mark Halvorsen to put
5 these studies together so that they could be delivered
6 to Schering-Plough so that they could launch --
7 hopefully launch the product in Europe.

8 MR. CURRAN: Thank you, Your Honor.

9 JUDGE CHAPPELL: Re-recross limited to the
10 re-redirect?

11 MS. BOKAT: Whatever it is, yes, please.

12 FURTHER RECROSS EXAMINATION

13 BY MS. BOKAT:

14 Q. Mr. Kralovec, when were you urging Mr.
15 Halvorsen to complete those studies for Schering?

16 A. Starting in the spring of 1998.

17 Q. And when did that end?

18 A. My understanding was the studies were finally
19 totally compiled and in suitable form very close to
20 this period of time.

21 Q. Close to October '98?

22 A. Yes.

23 MS. BOKAT: Thank you. Nothing further, Your
24 Honor.

25 MR. CURRAN: Nothing further, Your Honor.

1 Thank you.

2 JUDGE CHAPPELL: Thank you, Mr. Kralovec.

3 You're free to go.

4 THE WITNESS: Thank you.

5 MR. CURRAN: Your Honor, may we call our next
6 witness?

7 JUDGE CHAPPELL: Yes.

8 MR. CURRAN: Your Honor, at this time,
9 Upsher-Smith calls Mr. Scott Gould, and Mr. Carney of
10 my office, whom you know, will conduct this
11 examination.

12 MR. CARNEY: Good afternoon, Your Honor.

13 JUDGE CHAPPELL: How are you doing?

14 Raise your right hand, please.

15 Whereupon--

16 SCOTT A. GOULD

17 a witness, called for examination, having been first
18 duly sworn, was examined and testified as follows:

19 JUDGE CHAPPELL: Thank you, have a seat.

20 State your full name for the record, please.

21 THE WITNESS: Scott Ainsworth Gould.

22 JUDGE CHAPPELL: Thank you.

23 MR. CARNEY: Good afternoon, Your Honor, if I
24 could just approach the witness for a moment and hand
25 him the exhibit binder for this witness.

1 JUDGE CHAPPELL: You may.

2 DIRECT EXAMINATION

3 BY MR. CARNEY:

4 Q. Mr. Gould, by whom are you presently employed?

5 A. Upsher-Smith Laboratories.

6 Q. And what is your position at Upsher-Smith?

7 A. Purchasing manager.

8 Q. And when did you first start working at

9 Upsher-Smith?

10 A. I was hired by Upsher-Smith in March of 1988.

11 Q. And what positions have you held at

12 Upsher-Smith?

13 A. I was hired as purchasing agent, and in 1996, I
14 was promoted to purchasing manager.

15 Q. And as a purchasing agent, what were your
16 responsibilities?

17 A. My major responsibilities were sourcing and
18 placing orders for raw materials and packaging and
19 scheduling deliveries to meet the manufacturing
20 schedule.

21 Q. And then as a purchasing manager, what were
22 your responsibilities?

23 A. Well, my department has grown. Accounts
24 payable at that time was now reporting to myself. I
25 also had two purchasing agents that I had hired, and

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1 besides my other duties, I also managed the department.

2 Q. Does Upsher-Smith have project teams?

3 A. Yes, they do. They have both new product
4 development teams and launch teams.

5 Q. And have you ever been a member of a project
6 team or a launch team?

7 A. Yes, I've been members of both those.

8 Q. And about how many have you been involved with
9 in your time at Upsher-Smith?

10 A. I would estimate somewhere in the neighborhood
11 of 20.

12 Q. And what are the typical activities of a launch
13 team?

14 A. Well, a product launch team would first set a
15 time line and lay out tasks that needed to be completed
16 to get us to the launch, and then each department would
17 perform the functions that they have the expertise in.
18 What purchasing would do would be working with the
19 suppliers to schedule delivery to meet the
20 manufacturing schedule. If there was a contract
21 manufacturer involved, purchasing would be working with
22 the contract manufacturer, placing orders for
23 production and working on contracts if a contract would
24 be necessary.

25 Q. Did you have any involvement with the Klor Con

1 M product?

2 A. Yes, I was on both the Klor Con M development
3 team and the Klor Con M launch team.

4 Q. And when did you first become involved?

5 A. With the launch team?

6 Q. Well, with Klor Con M.

7 A. I believe the Klor Con M development team was
8 started sometime in 1994, and the Klor Con launch team
9 was started May 1st of 1999.

10 Q. And what was the role of purchasing in the Klor
11 Con launch team?

12 A. What I was doing was working very closely with
13 IPC. They're the contract manufacturer that we're
14 using to make the granules, and what I was doing was
15 discussing capacity issues with them.

16 Q. In 1999 after May 1st, what percentage of your
17 time was -- were those efforts with IPC taking up?

18 A. I would estimate that I was spending between 40
19 and 60 percent of my time on the Klor Con M project.

20 Q. And was anyone else on -- from purchasing
21 helping you with that?

22 A. Nobody else was. This was a very important
23 project for Upsher-Smith, and I felt that it was
24 something that could not be delegated to other
25 employees.

1 Q. And how often did the launch team meet in that
2 time, meaning the second half of '99?

3 A. We met approximately every other week.

4 Q. And did you receive any communications or
5 updates as a member of the launch team?

6 A. Yes, after each meeting, the members of the
7 team would receive notes that covered the discussions
8 that took place at the meeting.

9 Q. All right. Did you regularly attend those
10 meetings?

11 A. I attended most of them.

12 Q. If you didn't attend those meetings, did you
13 have a way of finding out what happened at them?

14 A. Yes, I would receive notes the next day as to
15 what was discussed.

16 Q. Besides the meetings, the formal meetings every
17 couple of weeks, how -- were there any other
18 communications between team members?

19 A. Yes, if any events or any new information came
20 to light, the various departments that were involved in
21 the team would be working in their own area, and if
22 some of that happened, something that was important to
23 the team, then they would send a -- generally it was an
24 e-mail would be sent to all the team members.

25 Q. And do you know when Upsher-Smith's Klor Con M

1 product was first commercially marketed?

2 A. Yes, September 1st, 2001.

3 Q. And how long did it take the launch team to put
4 together the launch of Klor Con M?

5 A. Well, the launch team was formed in -- on May
6 1st of 1999, so it took us approximately two and a half
7 years to be ready for that launch.

8 Q. And how does that two-and-a-half-year launch
9 compare to any of the launches you've been involved
10 with at Upsher-Smith?

11 A. Well, it was by far the biggest launch that
12 Upsher-Smith ever had.

13 Q. Why did it take -- why did it take that much
14 longer?

15 A. Well, the volume of tablets that needed to be
16 ready for the launch was very large, somewhere in the
17 neighborhood of 100 million tablets. We were working
18 with a contract manufacturer. The contract
19 manufacturer did not have the capacity to be able to
20 manufacture enough granules for us, so we had to work
21 with that contract manufacturer to get dedicated
22 equipment available that we could manufacture full-time
23 on.

24 We also had to put an addition onto
25 Upsher-Smith's facility to be able to manufacture at

1 Upsher-Smith the tablets.

2 Q. Were you --

3 A. I believe we spent about \$2.75 million
4 upgrading the IPC facility and we spent almost \$7
5 million on the Upsher-Smith facility.

6 Q. By way of comparison, what was the next biggest
7 launch prior to 2001 that Upsher-Smith had done?

8 A. I believe that was the Pacerone that took place
9 in May of 1998.

10 Q. And how many tablets were involved in the
11 Pacerone launch?

12 A. I think, and I'm not positive, but I think it
13 was in the neighborhood of 25 million tablets, compared
14 to the 100 million tablets that were needed for the
15 launch of the Klor Con M.

16 Q. And has there ever been another launch at
17 Upsher-Smith where Upsher-Smith had to specifically
18 make additions to its facility for the launch?

19 A. No, there has not. We have done some additions
20 to the Upsher-Smith facility, but that was not related
21 to a launch. It was just due to overall growth of the
22 organization.

23 Q. Now, you mentioned 100 million tablets. Did
24 you really need 100 million tablets for the commercial
25 launch on September 1?

1 A. Well, we had slightly over 100 million tablets
2 when we launched on September 1st. Within four days of
3 that launch, we had taken orders for 120 million
4 tablets. So, we went on back order at that time, and
5 we have been working for the last six months, and we
6 still are on back order.

7 Q. Now, earlier you mentioned a company called
8 IPC. Who is IPC?

9 A. IPC is a contract manufacturer. IPC actually
10 stands for International Processing Corporation, and
11 they're located in Winchester, Kentucky.

12 Q. How big a -- how big a company is IPC? And I'm
13 asking about 1999.

14 A. Well, in 1999, IPC was privately held, and I
15 believe that their total sales were under \$20 million.

16 Q. Do you know how Upsher-Smith decided on May 1,
17 1999 as the start date for the launch of the Klor Con
18 M20 product?

19 A. Well, we knew when we were going to launch the
20 product September 1st of 2001, and we knew that there
21 was going to be some capacity issues at both IPC and
22 Upsher-Smith. We wanted to allow ourselves plenty of
23 time to prepare for this launch. So, we started
24 roughly two and a half years ahead of time thinking
25 that that would give us plenty of time to be ready for

1 the launch, and as it turned out, we were really under
2 the gun and we were really pushing the entire time in
3 order to have the launch quantities available.

4 Q. Okay, and before I ask you about the steps of
5 that launch, I'm going to ask you a little bit first
6 about the process for making Klor Con M. Are you
7 generally familiar with the production process for Klor
8 Con M?

9 A. Yes, I am.

10 Q. Can you explain generally what the first step
11 is? Where does it all start?

12 A. Well, it really starts with Reheis. Reheis is
13 located in Midlothian, Texas, and Reheis is a
14 manufacturer of the USP potassium chloride that's the
15 active ingredient in the Klor Con M, and Upsher-Smith
16 purchases that from Reheis, has Reheis ship it to IPC.

17 Q. Now, once it gets to IPC, what's the first step
18 at IPC?

19 A. Well, IPC has to do a chemical test to assure
20 that it meets the specification, and that takes
21 approximately a week.

22 Q. And then once that's been done, what's the next
23 step?

24 A. Well, then what IPC does is they load the
25 potassium chloride into a Wurster, and what -- let me

1 just explain what a Wurster is, is a very large bowl,
2 and it slides into a fluid bed --

3 Q. What's a fluid bed?

4 A. A fluid bed is a big round stainless steel
5 cylinder basically is the best way I can explain it.
6 It's about two stories high. And the way it works is
7 that you have air that flows through -- up through the
8 Wurster and through the fluid bed, and it actually
9 lifts the potassium chloride crystals up and kind of
10 suspends them in the air. There's bonnets up on top,
11 which are like filters, and that keeps the crystals
12 from being blown out of the unit.

13 Q. And once you've got these crystals bouncing
14 around in the Wurster and the fluid bed, what's next in
15 the process?

16 A. Well, there's spray guns that are inside the
17 unit, and what they do is we actually spray the
18 solution that's in there that actually coats the
19 granules.

20 Q. And what's the purpose of the coating?

21 A. That gives us our release mechanism on the
22 crystals.

23 Q. And once the salt's been sprayed with the
24 coating, what's the next step?

25 A. Well, then what IPC does is they dump this

1 Wurster bowl out, they run it through a screen to take
2 out any large chunks, and they drum it off, and then
3 they review the batch record and make sure that the
4 batch records are filled out properly, they make sure
5 that there's not any accountability mistakes, and all
6 that takes approximately a week.

7 Q. And once they've got that done, what happens
8 next?

9 A. Then they ship it to Upsher-Smith.

10 Q. And once Upsher-Smith receives the coated
11 salts, what's the first step?

12 A. Well, what we do is we do an analytical testing
13 in our QC department, test the granules to make sure
14 that they meet our specifications.

15 Q. Okay. Once it's been QC'd for specs, what's
16 the next step?

17 A. Well, then what we do is we take these
18 granules, and we put them into a mixer along with a
19 couple other ingredients, and this mixer is called a
20 Gemco. It's a big large mixer. It's probably about 15
21 feet tall and about 15 feet wide, and this Gemco spins
22 at a high rate of speed and actually mixes all these
23 ingredients together so we have a good, uniform
24 mixture.

25 Q. And once you've got the uniform mixture out of

1 the Gemco, what's the next step?

2 A. Then we load the powder mixture into totes. We
3 bring those up to the second floor of our manufacturing
4 area, and we feed them into a tablet press from up
5 above, and we actually compress the powder into
6 tablets.

7 Q. And then after the powder's been tableted, what
8 happens next?

9 A. Well, then it goes through testing again. Our
10 QC department has to do dissolution testing on the
11 tablets. That takes a couple weeks. And once we get
12 their approval, then we would take the tablets to the
13 bottling line and bottle them.

14 Q. And once you've got it bottled, is it done?

15 A. It's not done. It still has to go through some
16 additional testing, not analytical testing, but we have
17 to test to make sure that all the labels are on and
18 that they're correct and that inserts are attached and
19 that type of thing.

20 Q. Now, turning to the launch itself, starting on
21 May 1, 1999, what were the first steps for
22 Upsher-Smith's launch team towards the commercial
23 launch of Klor Con M?

24 A. Well, what we did was we laid out tasks that
25 needed to be completed. We put together a time line.

1 Each department started working on their own job
2 functions. Sales and marketing were working on a
3 forecast. I was working with IPC on determining the
4 capabilities that they had to manufacture the product.

5 Q. And I'm going to ask you now to -- there's a
6 binder there I've put in front of you. Behind the
7 first tab is USX 378, if you could turn to that,
8 please.

9 Can you identify that document, please?

10 A. Yes, this is meeting notes that the team
11 members would receive after a Klor Con M meeting.

12 Q. And under that underlined part where it says,
13 "Scope," are these the items you were just talking
14 about?

15 A. Yeah, the scope are the major tasks that needed
16 to be completed by the team.

17 Q. And the second one there says, "Define launch
18 requirements."

19 What does that refer to?

20 A. Well, that would be something that sales and
21 marketing would have needed to do, was to come back to
22 the team and let us know what kind of launch quantities
23 were going to be required.

24 Q. Okay. And then going down to the fifth bullet
25 there, it says, "Alternate manufacturing site -- expand

1 capability at IPC (USL would subsidize)."

2 What's that referring to?

3 A. Well, that refers to some of the initial
4 conversations that I had with IPC, and we knew or I
5 found out that IPC had some capacity issues. I found
6 out that they probably would not be able to manufacture
7 the quantity of granules that was going to be necessary
8 for our launch. And one of the things that we were
9 doing were also looking at alternate contract
10 manufacturers.

11 Q. Was this the first time that that had come up,
12 the concern that they might not have the capacity at
13 IPC?

14 A. It did not. We knew when we were doing our R&D
15 trials back in '96 and '97 that there were capacity
16 issues at IPC.

17 Q. And if we go down to where it's underlined,
18 "Issues," and the fourth bullet there says, "USL
19 Equipment," and there's some more bullets, "press,
20 filling line, Gemco, space, and then Scott -- long lead
21 times to purchase equipment," does Scott refer to you?

22 A. Yes, it does.

23 Q. And what do those bullets refer to there under
24 USL Equipment?

25 A. Well, those are manufacturing items that we had

1 identified that were going to be capacity issues or we
2 felt may be capacity issues at Upsher-Smith to produce
3 the 100 million tablets. The long lead time that I
4 mentioned there was that most of these pieces of
5 equipment have very long lead times.

6 Q. Okay. Were there further meetings by the
7 launch team on these issues?

8 A. Oh, yeah. As I say, we met every other week
9 and discussed them.

10 Q. Let me ask you to turn to the next tab. It's
11 USX 414. When you've got that, if you could page in
12 about five pages to what is in very small letters
13 number Upsher-Smith-FTC-1000055, and at the top it
14 says, "June 3rd, 1999."

15 Do you recognize this document?

16 A. Yes.

17 Q. What is this?

18 A. Well, this is a -- some meeting minutes that
19 the team didn't have but the operations department had,
20 and they made minutes of their meeting and then gave it
21 to the Klor Con launch team.

22 Q. Where it says, "IPC Visit and Setup," were you
23 involved with this IPC visit?

24 A. Yes, I was.

25 Q. And what is the third bullet point there, where

1 it says, "IPC 5 lots equals 1 lot of USL"?

2 A. Well, what that refers to is that in our ANDA,
3 we were approved to make 180 kilo lots only, and at
4 Upsher-Smith, we were making 900 kilo lots. So, it
5 took five IPC 180 kilo lots to make one USL 900 kilo
6 lot.

7 Q. Was this a concern for Upsher-Smith?

8 A. The batch size at IPC was definitely a concern.
9 That was one of the things that we very early on
10 identified and were in discussions with IPC to scale
11 up. We felt that at 180 kilo batch size that we were
12 not going to be able to produce all the granulation
13 that was going to be necessary for the launch.

14 Q. And where it says, "Equipment," and it's
15 underlined, and then five bullet points down --

16 A. Yes.

17 Q. -- "Equipment needed, new press, Gemco bottling
18 line," does this refer to Upsher-Smith or IPC?

19 A. That refers to Upsher-Smith. All those are
20 pieces of equipment that we needed to buy to increase
21 Upsher-Smith's capacity.

22 Q. And that first bullet point under Equipment
23 where it says, "Current equipment -- good for
24 validation," what did that mean? It's right under the
25 word "equipment" there.

1 A. Well, I believe they're talking about the
2 equipment at Upsher-Smith. I mean, we had some tablet
3 presses and we had a Gemco, but, you know, we could
4 have done some validation batch -- validation on that,
5 but we didn't have the capacity to be able to do launch
6 quantities on our equipment.

7 Q. Okay. And then scrolling down to where it
8 says, "June 4, '99 Issues," the third bullet point
9 there says, "Must have contract with IPC (with QA
10 input) -- define things clearly," what did that mean?

11 A. Well, what that means is that quality assurance
12 wanted to make sure that everybody was aware that we
13 had to have a manufacturing contract with IPC to
14 specify in that contract certain quality issues. We
15 wanted to make sure that when the product was received
16 at Upsher-Smith that it was a quality product and could
17 be used without any problems in our facility.

18 We also wanted to have a contract with IPC
19 because we were talking to them about being a long-term
20 partner with us. We certainly did not want to rely on
21 them to be our main manufacturer for this Klor Con
22 granulation if after we got into it they decided that
23 they didn't want to do business with us or for whatever
24 reason. So, we wanted to make sure that they were
25 locked into a contract to produce the Klor Con

1 granulation for us for an extended period of time.

2 Q. Okay. And if you could flip about four pages
3 further into this document where it says, "Meeting
4 Notes, 7/20/99," and in very small writing, the Bates
5 number is Upsher-Smith-FTC-1000059, I believe. Looking
6 under where it says Meeting Notes, 7/20/99, the fifth
7 bullet point there says, "The cost of a new 32 inch
8 Wurster is approximately \$600K. This would be
9 necessary in order to get 20 weeks of time dedicated to
10 USL for Klor Con M."

11 What's that discussing?

12 A. Well, what they're talking about there is that
13 we knew that there were capacity issues. We had been
14 having meetings with IPC during this period of time,
15 and there were definitely capacity issues, and we were
16 asking IPC to give us some quotes on buying equipment
17 that could be installed at IPC and dedicated strictly
18 for Upsher-Smith's use so that we could produce a
19 quantity of material that was going to be required for
20 the launch.

21 And this also points out that it's a 32-inch
22 Wurster, which is a bigger unit. This will allow us to
23 scale up to a bigger batch size than what was currently
24 available at -- that we were currently approved with in
25 the 180 kilo size.

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1 Q. Okay, if you could turn to the next tab, which
2 is USX 751, a document at the top, "Klor Con Team
3 Meeting Notes 8/3/99."

4 Do you recognize this document?

5 A. Yes, this is meeting notes from one of the
6 launch team meetings.

7 Q. And about halfway down it says, "IPC Update,"
8 and the third bullet says, "Nancy W will follow up with
9 Scott G regarding Wurster availability."

10 What were you doing at that time regarding
11 Wurster availability?

12 A. At this time we were trying to schedule some
13 time at Upsher -- excuse me, at IPC for some scale-up
14 trials. IPC did have some Wursters, but they were
15 being used most of the time with other IPC customers,
16 and you can see here they talk about a 380 kilo batch
17 size to do these trials in, and at one time we were
18 thinking that maybe the largest batch size that we were
19 going to be able to do was 380 kilos. When we did do
20 the trials, we found out we could go as large as 400
21 kilos.

22 Q. Below that there's a "Production" that's
23 underlined and "Equipment," and the second point says,
24 "Gemco -- still researching since it would include
25 50/60 FT addition to building. If we do not purchase

1 Gemco, we would be at 100 percent capacity."

2 What does that refer to?

3 A. Well, what they're talking about there is our
4 current Gemco -- if we did not purchase a new Gemco,
5 our present Gemco, building this launch quantity would
6 be at 100 percent capacity, which means that if we
7 needed to produce anything more, we would not be able
8 to do it in this Gemco, and as everybody knows, an
9 addition to a building is extremely expensive, and we
10 were hoping that we could get by without doing an
11 addition to the building.

12 Q. Okay. And as part of this addition to the
13 building and the Klor Con line, did Upsher-Smith have
14 to hire any additional staff?

15 A. Yes, we did. I know we had to hire staff in
16 manufacturing, we had to hire staff in distribution,
17 quality control we had to hire staff.

18 Q. If you turn to the next page of the document,
19 it says, "Distribution," and then at the fifth bullet
20 point it says, "25% more space required on a monthly
21 basis."

22 What does this refer to?

23 A. Well, this refers to our warehouse. We
24 actually have two buildings at Upsher-Smith, we have
25 the manufacturing building and then we also have

1 another building that contains the warehouse and
2 distribution, and what we were calculating there,
3 because we were going to be building these -- this 100
4 million tablets over a long period of time in order to
5 get it ready for our launch, we were going to have to
6 have some place to store all these finished goods. And
7 what we were doing here early on is doing a calculation
8 to find out where we were going to store all the
9 finished goods.

10 Q. Okay. And after that August meeting, did you
11 have any further communications with IPC?

12 A. Yes, we were working with IPC on doing some
13 trials for scale-up, and we were also working with IPC
14 on trying to get some quotes as to what was going to be
15 required to get dedicated equipment into their
16 facility.

17 Q. Let me ask you to turn to the next tab in the
18 binder, and that's USX 509. Would you take a minute
19 and look at that document and identify it for me,
20 please.

21 A. Yeah, what this is is a letter that I received
22 from IPC with some various scenarios as to mixing time
23 and batch sizes with a 32-inch Wurster and also a
24 46-inch Wurster. Then there's also some estimated
25 pricing as to what the final granulation would cost

1 Upsher-Smith.

2 Q. So, the launch team started on May 1st, and
3 here we are in August, and you're still trying to
4 figure out which Wurster you need?

5 A. Yes, that is correct. We -- we were not sure
6 about the scale-up and how large we could go, whether
7 we needed a 32-inch Wurster or a 46-inch Wurster. We
8 really preferred to go with a 46-inch Wurster, but
9 their -- we were looking really throughout the world
10 trying to find somebody with a 46-inch Wurster that we
11 could do some trials in. We were really afraid that
12 our product would not work in a 46-inch Wurster,
13 because it was so big.

14 Q. Could you find one anywhere in the Continental
15 U.S.?

16 A. As far as we knew, no one in the Continental
17 United States even had a 46-inch Wurster, and we were
18 trying to find throughout the world somebody who would
19 allow us to come in and do some scale-up trials and
20 were unsuccessful at doing that.

21 Q. Okay, if you could turn to the next tab, USX
22 508, if you could look at this document and identify it
23 for me, please, and it's 508.

24 A. Yes, this is another letter from IPC talking
25 about coming to Upsher-Smith for a meeting to discuss

1 cost issues on equipment that would be needed at IPC to
2 get dedicated production.

3 Q. And there are two pages attached to this
4 document. What are those pages?

5 A. What those are are some preliminary estimates
6 that IPC had made for me as to what equipment would be
7 necessary to get this dedicated production and what the
8 cost would be, and there's one here for the 32-inch
9 Wurster as well as the 46-inch Wurster.

10 Q. Now, I'm looking at the first of those two
11 attachments. It's on USL 07440, and it looks to me
12 like there's more than just a Wurster listed there. It
13 seems like there are numerous things.

14 A. Oh, yeah, we needed more than just a Wurster to
15 produce our product in the quantities that we needed.
16 IPC, you can see -- well, one of the very expensive
17 items here is an incinerator or oxidizer it's called.
18 IPC's current equipment was running at near capacity,
19 and if we were to put in additional production that
20 Upsher-Smith needed, they needed to purchase all of
21 this type of equipment to be able to manufacture.

22 Q. Okay. And this letter is dated September 1,
23 1999?

24 A. Yes, it is.

25 Q. Okay. Can you turn to the next tab, please,

1 CX 622, and if you go halfway into it to the page
2 that's marked Upsher-Smith-FTC-088490, and at the top
3 you'll see it says, "Klor Con M Team Meeting, 9/8/99,"
4 are you with me?

5 A. Um-hum.

6 Q. Okay. Halfway down the page, it says, "IPC,"
7 bullet point, "IPC will be at USL on September 16 to go
8 over proposal to purchase a Wurster." The next bullet,
9 "Scott G will put together the agenda for the visit."

10 Do you know if this visit on September 16th
11 occurred?

12 A. Yes, it did.

13 Q. And the next indented bullet there says,
14 "Payback program will be negotiated." Then below that,
15 "Discuss actual lead times."

16 What do those points refer to?

17 A. Well, we knew that Upsher-Smith was going to
18 have to loan IPC funds to purchase this equipment and
19 put the expansion onto the IPC facility to give us the
20 production that was going to be required, and we wanted
21 to, of course, be paid back, and that was one thing
22 that I wanted to discuss with them, was that -- how we
23 were going to get that pay-back and how quickly we
24 could get it.

25 Q. And then with the actual lead times, what does

1 that mean?

2 A. I believe that is lead times on the equipment
3 that they were quoting on. We needed to discuss that
4 in the meeting, because I knew that some of the
5 equipment, especially like a Wurster, has extremely
6 long lead times.

7 Q. What's an extremely long lead time?

8 A. Well, the Wurster is actually manufactured in
9 Germany, and it's custom manufactured. They don't have
10 anything in stock. It's made to order, and the lead
11 time was six to eight months on a Wurster.

12 Q. So, you couldn't just get a Wurster at Home
13 Depot?

14 A. No.

15 Q. Going back further towards the top of the
16 document, it says, "Presentation to senior management,"
17 bullet, "Bob Clark will pick a couple of people from
18 the team to present information to senior management,"
19 and then the bullet points below that, if you go down
20 to the third one, it says, "Purchase of a new press,"
21 and the fourth one, "Purchase of a Gemco is necessary
22 for us to maintain our current business practices."

23 Do you know what this referred to?

24 A. Yes, the product launch team was discussing
25 spending some extremely large amounts of money for

1 Upsher-Smith to be able to launch the Klor Con M
2 product, both at IPC and at Upsher-Smith, and we wanted
3 to make sure that senior management was fully aware of
4 the discussions that were going on as far as the
5 capital expenditures that were going to be required.
6 So, the team kind of elected Bob Clark to spearhead
7 that and make a formal presentation to senior
8 management.

9 Q. So, you weren't going to purchase the press or
10 the Gemco prior to this meeting?

11 A. The group was discussing the need to be able
12 to -- to purchase it in order to build the 100 million
13 tablets, but we could not purchase it without the okay
14 from senior management.

15 Q. And earlier, I think you said this was an
16 extremely large amount of money for Upsher-Smith. How
17 much money are we talking about for this decision?

18 A. Well, the expansion and purchase of equipment
19 at IPC totaled \$2.75 million, and the equipment and the
20 expansion at Upsher-Smith totaled \$7 million. So, we
21 were talking about some extremely large spends for a
22 company our size.

23 Q. Okay. And then shifting back down towards the
24 bottom of the page, under IPC, the second bullet there
25 on the margin, it says, "Brad C will go to IPC on

1 October 4 to run trials to determine scale-up using
2 32-inch Wurster."

3 What did that refer to?

4 A. Well, we were approved at IPC to only do 180
5 kilo batches, and we were quite aware of the launch
6 quantities that were going to be needed, 90 to 100
7 million tablets, and we were not going to be able to
8 make that quantity of granules at IPC at 180 kilos per
9 batch. So, we were going to IPC to scale up to a
10 larger batch size, and that's what was eventually --
11 that work eventually determined that we could go to a
12 400 kilo batch size and a 32-inch Wurster.

13 We also knew that we could go larger than that,
14 and we did want to go larger than that, because when we
15 looked at the forecast extending out into 2003, even at
16 400 kilos, we wouldn't have the capacity to be able to
17 manufacture the quantity that was necessary.

18 Q. Did you know if you could go larger than 400
19 kilos at that time?

20 A. At that time, we did not, and that's why we
21 were looking for a 46-inch Wurster where we could do
22 some trials, and eventually we decided that we were
23 just going to go ahead and buy a 46-inch Wurster.

24 Q. What is the largest lot that you could do on a
25 46-inch Wurster, at least at --

1 A. Well, we didn't know at that time, but we were
2 estimating somewhere between 700 and 800 kilos, and
3 when we did do a trial, we were successful at doing 800
4 kilo batch sizes in the 46-inch Wurster.

5 Q. And if you got the batches up to 800 kilos, how
6 would that compare to an Upsher-Smith lot?

7 A. Well, an Upsher-Smith lot is 900 kilos, so it's
8 pretty close. It's not quite. We would have to use,
9 you know, a little over one batch, IPC batch, to make
10 an Upsher-Smith batch.

11 Q. Now, if you turn the page, please, the second
12 page says, "Alternative," near the bottom, "Alternative
13 site is needed for negotiating power." The next bullet
14 says, "Scott G is still pursuing Aeromatic as an
15 alternative site."

16 What are those alternatives that are referred
17 to?

18 A. Well, at this point we were still looking for
19 another contract manufacturer that had the capability
20 to produce the quantities of granules without
21 Upsher-Smith having to fund a expansion. So, there
22 were several members of the team, people within
23 Upsher-Smith, that were looking for alternative
24 manufacturers. I was looking, Chuck Woodruff and Paul
25 Kralovec went to The Coating Place and looked at that,

1 and Bill Tourek, who was our director of R&D, was also
2 looking for another contract manufacturer.

3 Q. Okay, I'm going to ask you now to skip one tab
4 and go to the tab after that, which is USX 1553, and
5 it's -- can you tell me what that document is?

6 A. Yeah, this is a memo or a letter from Bill
7 Tourek mentioning four different contract manufacturers
8 that he was aware of and was talking to them to see if
9 they had the capability of manufacturing for
10 Upsher-Smith. And it did eventually turn out that we
11 could not find another contract manufacture for one
12 reason or another. There were a number of different
13 reasons. Some of them didn't have Wursters. Some of
14 the contract manufacturers couldn't use solvents in
15 their facility. The Coating Place, actually our
16 quality assurance department went to The Coating Place
17 and did an audit on them and found that they were not
18 acceptable as far as quality standards go. So, we were
19 back to relying on IPC.

20 MR. CARNEY: Your Honor, at this time I'd like
21 to move for the admission of USX 1553 into evidence.

22 MS. BOKAT: No objection.

23 MS. SHORES: No objection.

24 JUDGE CHAPPELL: USX 1553 is admitted.

25 MR. CARNEY: Thank you, Your Honor.

1 (USX Exhibit Number 1553 was admitted into
2 evidence.)

3 BY MR. CARNEY:

4 Q. Now, in September, what was happening with IPC
5 and the status of negotiations with them after the
6 September 16 meeting?

7 A. They were in the process of putting together a
8 proposal to do an engineering study. I told them that
9 we needed firm costs as to what the equipment was going
10 to cost Upsher-Smith that they were looking at
11 purchasing to give us a dedicated manufacturing.

12 Q. And let me ask you to turn now back a tab to
13 USX 510, if you could identify that document for me,
14 please.

15 A. Yeah, this is the proposal for the engineering
16 study that I received September 24th, 1999.

17 Q. And if you could turn in it to what is marked
18 at the bottom as page 3 of 6, and you'll see it says,
19 "2, Preliminary Engineering Study Scope of Supply," and
20 there's below a list of items starting with 2.1 and
21 going onto the next page to 2.18. What are those
22 items?

23 A. These were some of the major pieces of
24 equipment, the major tasks that needed to be completed
25 in this engineering study. These were the major things

1 that the engineering study was going to cover that they
2 were going to look at.

3 Q. And did Upsher-Smith approve this engineering
4 proposal?

5 A. Yes, the proposal we did. IPC needed to hire
6 an outside engineering firm actually to come and do
7 this study in their facility, and it was going to cost
8 \$32,000, and Upsher-Smith did issue a PO and paid for
9 that engineering study.

10 Q. Okay, now, once you had this engineering study
11 commissioned and approved, were you committed to using
12 IPC at that time?

13 A. Once -- ah, no, we were not committed at this
14 point. We still could have gone someplace else at this
15 point.

16 Q. And in fact, you were looking at other
17 places --

18 A. Yes, we were.

19 Q. -- as you discussed? Yeah.

20 What was the next step once you had the
21 engineering proposal in place as far as IPC
22 negotiations went?

23 A. Well, we were pushing IPC to get this
24 engineering study completed just as quickly as
25 possible, because we knew that, again, some of the

1 equipment had some long lead times, and we wanted to
2 get that on order. We knew that time was starting to
3 get short, that we were going to need seven, eight
4 months worth of manufacturing at IPC.

5 Q. Did you set a date for them with regard to
6 getting the engineering proposal done?

7 A. Yeah, I had asked them to put the engineering
8 study together and have it to me by December 1st, and I
9 attempted to put a penalty in that if they did not have
10 it to pay, that they would have to pay a penalty.

11 Q. Okay. And did you -- were you able to get that
12 penalty clause?

13 A. I was not.

14 Q. Okay. And when ultimately did you get the
15 engineering study from them?

16 A. I finally received the engineering study in
17 January of 2000.

18 Q. And once you had the -- what was -- what was
19 Upsher-Smith's reaction to the engineering study?

20 A. Well, we -- we were a little bit shocked
21 that -- at the cost. The engineering study came back
22 that it -- that the cost was going to be \$2.6 million.
23 The original estimate that we had received from IPC was
24 going to be between \$1.5 and \$2.5 million, and we were
25 hoping that it would be down more towards the \$1.5

1 million.

2 Q. And did you immediately agree to the
3 engineering study?

4 A. We had some discussions with IPC about the
5 engineering study, and one of the -- one of the things
6 that we felt was that IPC wanted to have a lot of bells
7 and whistles on some of their equipment, but eventually
8 we did agree to go ahead and sign the engineering
9 study.

10 Q. They convinced you that the bells and whistles
11 were necessary?

12 A. Yeah, they did. It -- some of the things were
13 upgrades that really helped their manufacturing
14 process, it speeded things up and made it quicker, like
15 a bulk alcohol tank farm that was in the proposal.
16 That allowed us to buy cheaper alcohol and actually
17 paid for itself or will pay for itself within a year.

18 Q. At this point, did you sign a manufacturing
19 agreement with them and start the process rolling?

20 A. What we did, we were in negotiations on a
21 manufacturing agreement, and because of the rush to get
22 some of the equipment on order as quickly as possible,
23 we drew up a letter of intent, which spelled out what
24 Upsher-Smith was going to loan IPC. It also spelled
25 out the manufacturing costs that IPC was going to

1 charge Upsher-Smith.

2 Once we signed this letter of intent, that
3 committed IPC to be Upsher-Smith's partner to
4 manufacture the Klor Con M granulation.

5 Q. Okay, I'm going to ask you to turn to what is
6 tab USX 812 in your binder, if you could take a look at
7 that and identify that for me, if you would.

8 A. Yes, this is the letter of intent that
9 Upsher-Smith drew up and sent to IPC.

10 Q. And you were involved in the negotiations of
11 this letter of intent?

12 A. Yes.

13 MR. CARNEY: Your Honor, at this time we would
14 move for the admission of USX 812 into evidence.

15 MS. BOKAT: No objection.

16 MS. SHORES: No objection.

17 JUDGE CHAPPELL: USX 812 is admitted.

18 (USX Exhibit Number 812 was admitted into
19 evidence.)

20 BY MR. CARNEY:

21 Q. Now, if you could turn to the second page of
22 the document where it says, "2, Current Financing for
23 Certain Equipment: IPC and USL understand that it is
24 important to the Transaction that IPC's facility is
25 fully functional for the manufacture and supply of the

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1 Product to USL on or before November 7, 2000, with
2 USL's availability to undertake its scale up and
3 validation of USL's processes commencing on or before
4 January 7, 2001."

5 Do you know who pushed to have that sentence
6 put in the document?

7 A. Upsher-Smith did. We needed to have IPC finish
8 all of their expansion, purchase all of the equipment
9 and have it all installed so that we could start
10 commercial production no later than November 7th,
11 because we knew that if we did not start by then, we
12 would not be able to manufacture the launch quantities
13 that were required, the 100 million tablets, and we
14 wanted to make sure that it was fully understood with
15 IPC that they had to have this done just as quickly as
16 possible.

17 Q. Okay. And on the next page it says, "3.1,
18 Manufacture and Purchase," and then about eight lines
19 down, you'll see the familiar language, "IPC's facility
20 will be fully functional for the manufacture and supply
21 of the products to USL on or before November 7, 2000,
22 and USL's availability to undertake its scale up and
23 validation of USL's processes commencing on or before
24 January 7, 2001."

25 Do you know why that same language appears

1 twice in the document?

2 A. Well, again, it was just to re-emphasize the
3 importance that we had to start manufacturing in
4 January.

5 Q. Okay. And once you had this agreement in
6 place, what was the next step now?

7 A. We were in negotiations on a manufacturing
8 agreement with IPC. Also, IPC immediately ordered the
9 Wurster, they ordered an oxidizer, and they ordered a
10 large air compressor that were all needed, and those
11 were the items that had the longest lead times. Then
12 they also started with their blueprints and design of
13 the expansion at IPC.

14 Q. Why was the negotiation of the manufacturing
15 agreement taking so long?

16 A. It was a very complicated document. It
17 contained all of the pay-back from the loan that we
18 were giving to IPC, and we had to negotiate that. That
19 took a long time. Ken Olsen, who was the president of
20 IPC, was also the president of Glatt, which is located
21 in New Jersey. He also travels a lot, so there was a
22 delay in waiting for him to be in town so we could
23 negotiate with him. We had to negotiate all this with
24 Ken Olsen.

25 And it was -- it was a -- there was a lot of

1 quality issues. Those all had to be in this
2 manufacturing agreement document, and it was a long,
3 drawn-out process, but the important thing was we had
4 signed the letter of intent and had -- IPC was already
5 underway and working on their facility and ordering the
6 equipment that they needed.

7 Q. So, the negotiation of the manufacturing
8 agreement didn't hold up the --

9 A. It did not, and that's why we went ahead with
10 the letter of intent, so that nothing would be held up
11 while we were negotiating the manufacturing agreement.

12 Q. Okay, I am going to ask you to turn to the next
13 tab, which is USX 790. Can you identify this document
14 for me, please?

15 A. Yes, this is the manufacturing agreement that
16 was finally negotiated and signed off in May of 2000.

17 Q. Okay. And if you could turn to what is marked
18 as exhibit page 32 in this document, and it says,
19 "First Amendment to Manufacturing Agreement between
20 Upsher-Smith Laboratories and International Processing
21 Corporation."

22 What does this amendment deal with?

23 A. Okay, this is an amendment to the contract.
24 This came later on, and during the scale-up at IPC,
25 during the construction and the ordering of equipment

1 there, installation of the equipment, IPC was running
2 over budget. We had agreed to loan IPC \$2.6 million,
3 and they were running over that. So, what they did was
4 they came to us and requested additional funds for
5 additional pieces of equipment that were not identified
6 in the original engineering study that they had done.
7 And we did agree to loan them the additional \$150,000,
8 which brought the total loan to IPC from \$2.6 million
9 to \$2.75 million.

10 Q. And I'm sorry, when was this agreement signed,
11 the manufacturing agreement I mean?

12 A. The manufacturing agreement itself? I believe
13 that was signed in --

14 Q. Do you know what month?

15 A. -- in May of 2000.

16 Q. May of 2000, okay.

17 A. I believe. I don't see a date on here, but I'm
18 going by memory.

19 Q. Okay. Do you know what stability batches are?

20 A. Yeah, all of our products have an expiration
21 date on them, and we have to justify what that
22 expiration date is --

23 Q. You mean justify it to the FDA?

24 A. Yeah, justify it to the FDA, and what we have
25 to do is make stability -- a stability batch, put it up

1 on stability in a stability chamber, which is at high
2 humidity, high temperature, for three months, and then
3 test it, and if it tests out okay, that three months in
4 the stability chamber represents two-year expiration
5 dating at room temperature.

6 Q. Did you do stability batches for Klor Con M?

7 A. Yes, we did.

8 Q. When were those done?

9 A. Those were done in May of -- those were done in
10 May of 2000.

11 Q. Okay. And you said they would have taken about
12 four months with testing to complete?

13 A. Correct, yes.

14 Q. So, they were done in about September?

15 A. Yes.

16 Q. And could you have done commercial batches
17 before the stability batches were done?

18 A. No, we could not.

19 Q. Why not?

20 A. Well, we have to justify our stability to the
21 FDA before we can make commercial batches. Those were
22 also scale-up batches that were submitted in the 400
23 kilo lot size to the FDA, so we had not received
24 approval yet from the FDA on the 400 kilo batch size.

25 Q. So, it was with the batches made in May of 2000

1 that you got approval for the 400 kg with the FDA?

2 A. Yes.

3 Q. Let me ask you to turn to the next tab, which
4 is USX 374, and can you identify this document, please?

5 A. Yeah, this is the justification that IPC had
6 given us for the additional equipment that they needed
7 to purchase for the additional \$150,000 that they were
8 requesting.

9 Q. Okay. And it's captioned "Upsher-Smith Labs
10 Klor Con Project, Change in Scope Items, 7/11/00"?

11 A. Correct.

12 Q. What kind of things needed to be done in July
13 of 2000 that required the change of scope?

14 A. Well, what this letter is is just equipment
15 that was not identified in the engineering study. It
16 also includes some process control upgrade software to
17 meet some new FDA mandate, I guess, that had come out,
18 and that's why we felt that it was justifiable and did
19 agree to loan them the additional money.

20 Q. So, was IPC in July of 2000 still installing
21 items and doing construction?

22 A. Yes, they were.

23 Q. And do you know -- strike that.

24 Turning to Upsher-Smith's construction on its
25 facility, as of July 2000, do you know what the status

1 of that construction was?

2 A. Yes, in July of 2000 is when we actually broke
3 ground for the expansion. I do know that all of the
4 major pieces of equipment that we had to buy were
5 actually already ordered, and we were fully underway
6 getting prepared to start manufacturing for the launch.

7 Q. Okay, if you could turn to the next tab, USX
8 367, what is this document?

9 A. This is a letter that I received from Upsher --
10 from IPC in September saying that it looked like they
11 were on schedule to be completed the first part of
12 December, and there's a time line included here also.

13 Q. Okay.

14 Your Honor, at this time I'd move for the
15 admission of USX 367 into evidence.

16 MS. BOKAT: No objection.

17 MS. SHORES: No objection, Your Honor.

18 JUDGE CHAPPELL: USX 367 is admitted.

19 MR. CARNEY: Thank you, Your Honor.

20 (USX Exhibit Number 367 was admitted into
21 evidence.)

22 BY MR. CARNEY:

23 Q. Do you see the second sentence where it says,
24 "Lab 8 will be ready for production in the first week
25 of December"? Does that refer to December 2000?

1 A. Yes, it does.

2 Q. And was that on schedule according to
3 Upsher-Smith's expectations?

4 A. Yes, we wanted to start manufacturing no later
5 than January 1st, 2001, and we knew there had to be
6 some validation of their equipment, too, so we wanted
7 everything installed and ready to go by December 1st.

8 Q. And do you know when IPC finished with the
9 installation of equipment and construction?

10 A. It was all finished in December, and we
11 actually started commercial production, and I believe
12 it was December 15th, 2000.

13 Q. And between the finishing of the construction
14 and the beginning the production, the commercial
15 production in -- I'm sorry, when did you say the
16 commercial production started?

17 A. December 15th, I believe, 2000.

18 Q. 2000, okay. In that period, what was being
19 done in between the finishing of the construction and
20 the beginning of the commercial production?

21 A. Validating the new equipment at IPC.

22 Q. Is that required by the FDA?

23 A. Yes, it is.

24 Q. Okay. As of December of 2000, do you know what
25 the status of construction at Upsher-Smith was?

1 A. Yeah, I believe in December of 2000, the
2 construction was complete, and most of the equipment
3 that we had purchased was installed, and they were
4 going through validation of that equipment.

5 Q. Earlier you mentioned that there would be a
6 need or -- there would be a need for additional space
7 or storage space. Was that part of the addition at
8 Upsher-Smith?

9 A. No, the storage space of the finished goods
10 that we were talking about previously was storage of
11 the finished product, which was done at Building B,
12 which is our second building. All of the finished
13 product is stored over there. The addition to Building
14 A did contain some storage for the -- and that's used,
15 that's fully used for the drums of granules that come
16 from IPC and are waiting for QC testing and release
17 before we can start our processing phase.

18 Q. Were there any fixtures that had to be
19 installed in Building B for the storage?

20 A. Yeah, there was pallet racking, we needed to
21 put a lot of pallet racking in. We needed to put in
22 some high-density racks. We totally filled up the
23 warehouse with the finished goods that we had produced
24 preparing for the launch. And in fact, we did actually
25 lease a third building, a smaller building, and moved

1 some of the records and packaging material into that
2 building to make room in Building B for the finished
3 goods.

4 Q. Do you know if the -- well, let me ask you, I'm
5 not sure if I asked already, but when was the
6 construction completed at Upsher-Smith?

7 A. I believe the construction was completed in
8 December, and we started doing our validation on the
9 Gemco blender and the tablet press in January of 2001.

10 Q. And did you have to do validation work on that
11 equipment?

12 A. Yes.

13 Q. And when was the validation work on the
14 Upsher-Smith equipment completed?

15 A. The Gemco blender and the tablet press was
16 completed in February, and we immediately started
17 manufacturing tablets on those pieces of equipment.

18 Q. And was the construction finished on schedule?

19 A. Yes, it was. It was actually, at least from
20 what I heard, the construction was finished within five
21 days of the time line and within 5 percent of budget.

22 Q. Okay. Now, you said the validation was done in
23 February and March and the packaging. Do you know when
24 the first commercial bottle of Klor Con M20 came off of
25 the Upsher-Smith packaging line?

1 A. Yeah, it took us a little bit longer to get the
2 bottling line validated, and that was completed in
3 March, and the first filled bottle that came off the
4 bottling line was -- I believe it was March 28th of
5 2001.

6 Q. And does that bottle have an expiration date?

7 A. Yes, it does, two years.

8 Q. And where does that two years start at?

9 A. Well, the expiration date does not start when
10 the tablets are put into the bottle. The expiration
11 starts when the granulation is first made at IPC.

12 Q. Is there any other limit on the saleability of
13 a product based on expiration date?

14 A. Yes, almost all of our customers will not
15 accept a finished product that has less than one year
16 remaining on that expiration date.

17 Q. And did those expiration limits have any
18 significance on your production, expansion and ramp-up
19 decisions for Klor Con M20?

20 A. Yes, it certainly did. We certainly could not
21 manufacture product more than one year before the
22 launch; otherwise, that material would be -- would have
23 to be scrapped and could not be sold.

24 Q. Now, earlier you mentioned a May 2000
25 validation batch. Do you know if that May 2000

1 validation batch was used in the September 1 commercial
2 launch?

3 A. No, it was not. That was a validation batch
4 that we elected to produce at that time, and it had
5 over one year dating on it at the time of our launch,
6 so that material could not be sold and was scrapped.

7 Q. Now, once IPC had started commercial
8 production, what was its production schedule like over
9 the ensuing months?

10 A. IPC was producing five days a week 24 hours a
11 day pretty much continuously since the middle of
12 December, except for Christmas break there, but
13 starting in January right up until our launch.

14 Q. And did there come a time after the March 28th
15 first bottle off the line to the September 1 launch,
16 did there come a time when you were concerned about
17 meeting the launch quantity of 100 million tablets?

18 A. Yes, there definitely was. Somewhere around
19 the July time frame, we were worried that we weren't
20 going to be able to have the quantity that was needed
21 for the launch, and our real bottleneck was not at
22 Upsher-Smith in making the tablets, but the bottleneck
23 was at IPC and getting the granulations, and I did put
24 some plans in place with IPC to step up production. Up
25 until then, they were running five days a week, and we

1 made a decision to go seven days a week at IPC.

2 Q. Given those concerns, do you think it would
3 have been possible for Upsher-Smith to launch with
4 commercial quantities as early as June 1, 2001?

5 A. No, I don't believe we could have.

6 Q. Okay, I'm going to take you back now in time to
7 1997. In 1997, were you aware that there was patent
8 litigation regarding Klor Con M?

9 A. Yes, I was.

10 Q. And how were you aware?

11 A. I was a member of the new product development
12 team for the Klor Con M back then, and it was made --
13 the team was made aware of the litigation.

14 Q. And was there a launch team at that time for
15 Klor Con M?

16 A. No.

17 Q. And in May of 1997, were you asked to reserve
18 time to do validation batches at IPC?

19 A. I'm sorry, could you repeat that?

20 Q. Yes. In May of 1997, were you asked to reserve
21 time at IPC to do validation batches?

22 A. Yes, I was. The team had requested that I
23 reserve some time.

24 Q. And what time period were you reserving for
25 those validation batches?

1 A. I actually issued a purchase order to IPC for
2 those validation batches on -- to take place on June --
3 I think it was 17th to 18th, 19th, right in that time
4 frame, of 1997.

5 Q. And did you actually run those validation
6 batches in 1997?

7 A. No, we never did run them. They were moved
8 back at one point and then eventually cancelled.

9 Q. And why were they cancelled?

10 A. They were cancelled because we -- excuse me for
11 stuttering here -- they were eventually cancelled
12 because we had reached an agreement with Schering and
13 were not going to -- were not going to be able to make
14 any -- make any additional product for some time.

15 Q. And did you ever reserve time for commercial
16 batches, commercial quantities, of Klor Con M in 1997?

17 A. Yes, we were -- the team also had made a
18 recommendation when this patent infringement litigation
19 was going on that it might be a good idea to set some
20 time aside, because we knew that IPC had capacity
21 issues, and maybe we should reserve some time at IPC,
22 and I did at one time ask IPC just to hold the month of
23 August 1977 open --

24 Q. I'm sorry, what year?

25 A. 1997.

1 Q. Thank you.

2 A. -- hold the month of August open for some
3 production.

4 Q. And did you give them any money to hold that
5 date open?

6 A. Not at all. I had sent a -- after I had done
7 that, I had sent an e-mail to our executive management,
8 and I did have a conversation with Paul shortly after
9 that and was told by Paul that under no circumstances
10 should Upsher-Smith commit any funds for any
11 manufacturing at IPC at that time because of the
12 litigation that was going on.

13 Q. And that communication was in May of 1997?

14 A. I believe it was, yes.

15 Q. And by "Paul," you mean Paul Kralovec?

16 A. Yes.

17 Q. How much would it have cost Upsher-Smith in May
18 of 1997 to hold open the month of August to -- for
19 production?

20 A. Well, I think our manufacturing fee that
21 Upsher-Smith -- that IPC would have charged us was in
22 the neighborhood of \$300,000 if we were to run that
23 entire month.

24 Q. And you were told not to spend \$300,000 on --

25 A. I was told not to spend any funds at all.

1 Q. Okay. All totaled, how long did it take to
2 plan, negotiate and complete the expansion at IPC for
3 the Klor Con M launch?

4 A. Well, our launch team was formed in -- on May
5 1st of 1999, and we immediately started working with
6 IPC on getting ready for production, and we didn't
7 launch until September 1st, and we -- September 1st of
8 2001, and we were scrambling the whole time to get the
9 100 million tablets in our inventory.

10 Q. And what was the total cost for the IPC
11 expansion, including those change of scope items?

12 A. \$2.75 million.

13 Q. And could you have planned, negotiated and
14 gotten the expansion of IPC done any quicker?

15 A. I don't believe we could have.

16 Q. And Mr. Gould, was that expansion of IPC
17 necessary for the commercial quantities Upsher-Smith
18 needed for the pipeline fill and launch of Klor Con M
19 product?

20 A. Yes, I don't think we could have -- well, in
21 fact, I know we could not have reserved the time at IPC
22 to manufacture the quantity that we needed without the
23 dedicated equipment that we got, and even with the
24 dedicated equipment, we did have the forecasted
25 quantity in our inventory September 1st, but we did

1 sell over that.

2 MR. CARNEY: No further questions, Your Honor,
3 at this time.

4 JUDGE CHAPPELL: Before your cross -- well,
5 does Schering have any questions?

6 MS. SHORES: No, Your Honor.

7 JUDGE CHAPPELL: Mr. Curran, what's the status
8 of your out-of-state witness? No one's updated me.

9 MR. CURRAN: Your Honor, you may recall
10 originally we had hoped to have six witnesses on for
11 Thursday and Friday. We gave up, and we sent the
12 witness from Seattle, Washington home. We -- after
13 this witness is concluded, we do hope to have one more
14 brief witness today, and if you need any enticement, he
15 has a short videotape to show, so maybe that's a -- not
16 a bad way to spend a Friday afternoon.

17 JUDGE CHAPPELL: Well, let's take our afternoon
18 recess. Ms. Bokat, when we come back, you can begin
19 your cross.

20 MS. BOKAT: Thank you, Your Honor.

21 (A brief recess was taken.)

22 JUDGE CHAPPELL: Ms. Bokat?

23 MS. BOKAT: Thank you, Your Honor.

24 CROSS EXAMINATION

25 BY MS. BOKAT:

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 Q. Good afternoon, Mr. Gould.

2 A. Hello.

3 Q. The FDA requires that validation batches be
4 produced for a product, does it not?

5 A. Yes, it does.

6 Q. Upsher usually produces at least one validation
7 batch before filing an ANDA, correct?

8 A. Not necessarily. I don't -- I'm not sure. Not
9 to my knowledge.

10 Q. Does Upsher produce validation batches close to
11 the time of the launch?

12 A. Sometimes we do, but not always. With this --
13 with the Klor Con M in the 400 kilo batch size, we did
14 not.

15 Q. But you produced some at the other batch size?

16 A. In the 180 kilo batch size?

17 Q. Right.

18 A. We had scheduled some validation batches back
19 in June of 1997, but we never made them.

20 Q. You were also holding open time in August of
21 '97 at IPC for production of Klor Con M, right?

22 A. Correct.

23 Q. And the August production would have been used
24 for commercial launch, right?

25 A. That's why it was being held open, yes.

1 Q. Was the plan that the May validation batches
2 would also be used in commercial launch?

3 A. I believe if we would have launched back then,
4 but there were no plans, but if we would have, we
5 probably -- yeah, I'm sure we would have used them.

6 Q. And the goal is to produce such validation
7 batches close enough to the launch that you can use the
8 validation batches for commercial sale, right?

9 A. Well, that generally is the rule, yes, but also
10 consider the cost of the active ingredient in this
11 case, when we're talking about potassium chloride at a
12 dollar a kilo, where most active pharmaceutical
13 ingredients are \$200, \$300, \$400 a kilo. So, our
14 investment in the validation batches is much smaller in
15 this case than with many other pharmaceutical products.

16 Q. But the goal was still to use those validation
17 batches for commercial sale, correct?

18 A. In '97?

19 Q. Yes, sir.

20 A. Well, back in '97, there were no real plans for
21 a launch.

22 MS. BOKAT: Your Honor, may I approach the
23 witness, please?

24 JUDGE CHAPPELL: Yes, you may.

25 MS. BOKAT: It looks like we have it on the

1 screen, Your Honor.

2 JUDGE CHAPPELL: You are going to zoom that in,
3 aren't you?

4 MS. HERTZMAN: Sure.

5 JUDGE CHAPPELL: Thank you.

6 BY MS. BOKAT:

7 Q. CX 266 is a pair of e-mails, is it not?

8 A. Yes, it is.

9 Q. Looking at the second page, that's an e-mail
10 from you to Ms. O'Neill, Mr. Troup, Mr. Woodruff, Mr.
11 Kralovec and Ms. Dolan and Mr. Ritland?

12 A. That is correct.

13 Q. That e-mail is dated May 15th -- excuse me, May
14 13th, 1997?

15 A. Correct.

16 Q. In that e-mail, you inform the addressees that
17 you've scheduled Klor Con M validation batches at IPC
18 for June 17th through 19th, correct?

19 A. That is correct.

20 Q. You also inform them that IPC is holding open
21 the month of August for production of launch
22 quantities.

23 A. Yes.

24 Q. You had until May 15th to confirm the August
25 production with IPC?

1 A. Yes.

2 Q. Otherwise, was IPC going to reschedule its
3 facilities for other customers?

4 A. Yes, they were.

5 Q. Did you ask for an extension on the hold for
6 the August production?

7 A. I believe I did mention that to IPC, that I
8 would like them to hold it open longer, and the
9 response that I got back from IPC was that they would
10 try, but they would not make any promises.

11 Q. Originally, they wanted confirmation from you
12 by May 15th, right?

13 A. Correct.

14 Q. Were you asking that they give you an extension
15 until May 21st?

16 A. I don't remember offhand what the date was that
17 I'd asked for an extension, but -- oh, I see down here.
18 I may have asked them if they could hold it until the
19 21st.

20 Q. Was the request for the extension because of a
21 meeting Mr. Troup was going to be having with
22 Schering-Plough?

23 A. I'm not -- I'm not -- I don't remember about a
24 meeting that Ian Troup was having. I'm not sure.

25 Q. If you look at the handwriting on that page,

1 there's an entry that says, "5/15/97, Ian is scheduled
2 to meet w/Key re: a settlement 5/21/97."

3 Does that refresh your recollection about why
4 you asked for an extension on the confirmation of the
5 hold?

6 A. No, it does not. That is not my writing.

7 Q. And it doesn't refresh your recollection?

8 A. I don't -- no, it doesn't. Ian did not keep me
9 abreast of any of his meeting schedules.

10 Q. And when you say "Ian," you're referring to Mr.
11 Troup?

12 A. Yes.

13 Q. Would you look at the first page of CX 266,
14 please?

15 A. Yes.

16 Q. That's another e-mail from you, is it not?

17 A. Yes, it is.

18 Q. This one is addressed to Denise Dolan?

19 A. Correct.

20 Q. And is dated May 19th, 1997?

21 A. Correct.

22 Q. In it you inform Ms. Dolan that you had talked
23 to -- it says a George T. Who's George T?

24 A. That's George Tomaich, he is the president of
25 IPC.

1 Q. So, you're informing Ms. Dolan that you spoke
2 to Mr. Tomaich on May 15th, right?

3 A. Correct.

4 Q. About holding August open?

5 A. Correct.

6 Q. And that was holding August open for your Klor
7 Con M20 launch quantities?

8 A. That's what the e-mail says, yes.

9 Q. Had you told Mr. Tomaich that you would call
10 him as soon as you heard after Mr. Troup's meeting with
11 Key?

12 A. George had told me that he would hold the month
13 of August open for only a limited period of time and
14 that I had told him that I would get back to him as
15 soon as I could. I see here it states after Ian's
16 meeting with Key, and I don't remember what that
17 meeting was about.

18 Q. You eventually got back to Mr. Tomaich, right?

19 A. I did, yes.

20 Q. And you cancelled the May validation batches.
21 Is that right?

22 A. Yes.

23 Q. After that, did IPC give its capacity to
24 customers other than Upsher-Smith?

25 A. I don't know for sure, but I would assume that

1 they did.

2 MS. BOKAT: Your Honor, may I approach the
3 witness again, please?

4 JUDGE CHAPPELL: Yes, you may.

5 BY MS. BOKAT:

6 Q. Mr. Gould, I hand you CX 261. It looks like we
7 have that on the computer.

8 CX 261 is another e-mail, is it not?

9 A. Yes, it is.

10 Q. From Brad Christenson?

11 A. Yes.

12 Q. Dated May 19th, 1997?

13 A. Correct.

14 Q. At that time, was Mr. Christenson an employee
15 of Upsher-Smith?

16 A. Yes, he was.

17 Q. What was his position in May of 1997?

18 A. I believe he was in our R&D department at that
19 time.

20 Q. Were you one of the recipients of this e-mail
21 message?

22 A. Yes, I was.

23 Q. Mr. Christenson refers to the June validation
24 lots for Klor Con M20.

25 A. Right.

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1 Q. And then he's saying that Upsher needs to
2 decide -- is it what size bottles those tablets would
3 be bottled in?

4 A. No, he states here -- well, yes, what SKUs --
5 what that means is that the validation lots have to be
6 divided up equally between all the bottle sizes that
7 Upsher-Smith is going to market the product in. That's
8 a requirement by the FDA.

9 Q. So, Mr. Christenson is saying that a decision
10 needs to be made about how to divide those validation
11 batches among the bottle sizes, right?

12 A. Correct.

13 Q. And then those bottles would then be sold
14 commercially?

15 A. Not necessarily.

16 Q. But they could be?

17 A. They could be.

18 Q. All right. When Upsher-Smith submitted its
19 ANDA for Klor Con M20, that was for a 180 kilogram
20 batch size, correct?

21 A. That is correct.

22 Q. And as of May 1997, Upsher was still planning
23 to use that batch size, correct?

24 A. That -- at that time, that was the only batch
25 size that we were approved to manufacture in, yes.

1 Q. The equipment for manufacturing the coated
2 crystals at IPC that would eventually become Klor Con
3 M20, that equipment as specified in Upsher's ANDA was
4 already installed and ready to go at IPC as of April
5 1997, was it not?

6 A. In the 180 kilo batch size, yes, you're
7 correct.

8 Q. In 1997, Upsher-Smith estimated that IPC could
9 produce 20 to 30 of those 180 kilogram batches per
10 week, correct?

11 A. I believe that's correct, yes.

12 Q. And that would be the equivalent of 7 million
13 tablets per week of Klor Con M20?

14 A. No, I don't agree with that. At 180 kilos per
15 batch size, 20 batches would produce 1.8 million
16 tablets. So, if it took them a week to do 20 batches,
17 then that's how long it takes them to do the 400 kilo
18 batch size, is 20 batches a week, that would yield 1.8
19 million tablets.

20 MS. BOKAT: Your Honor, may I approach the
21 witness again?

22 JUDGE CHAPPELL: Yes.

23 MS. BOKAT: I'll have to ask for Ms. Hertzman's
24 help with the ELMO on this one.

25 Would you like a hard copy, Your Honor, a paper

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1 copy?

2 JUDGE CHAPPELL: Not if it's on the ELMO.

3 BY MS. BOKAT:

4 Q. Mr. Gould, do you recall being deposed in this
5 matter in October 2001?

6 A. I certainly do.

7 Q. What I handed you is a transcript of that
8 deposition.

9 Would you turn, please, to page 66 in the
10 deposition, and would you look beginning at line 2.
11 Were you asked:

12 "QUESTION: As of June '97, at the 180-kilogram
13 batch size, what was IPC's annual capacity in terms of
14 tablets for Klor Con M?"

15 Then there were a couple of objections, and
16 then the answer:

17 "ANSWER: Well, at 180-kilo batch size, it
18 would take 15 batches to make one Upsher-Smith batch,
19 which is 442,000 tablets. IPC's maximum number of
20 batches that they've been able to produce so far in
21 2001 -- well, I shouldn't say the maximum. Their
22 average number of batches that they've been able to
23 produce in 2001 is 20 batches per week. So, that means
24 that add 180-kilo batch size, IPC would be able to
25 produce approximately -- I don't have a calculator to

1 figure it out exactly, but somewhere in the
2 neighborhood of 7 million tablets per week."

3 Was that your answer?

4 A. Yeah, that is my answer, and it is incorrect.

5 Q. I'm sorry, it's incorrect?

6 A. Yes.

7 Q. Did you correct it at that deposition?

8 A. I did not, no.

9 Q. By the time in 1999 when Upsher began planning
10 for its September 2001 launch of Klor Con M20, IPC had
11 increased its customer base, had it not?

12 A. I believe so.

13 Q. So, IPC in 1999 had more customers than they
14 did back in the spring of 1997.

15 A. You know, I'm just speculating at this point.
16 I really don't know anything about IPC's customers.

17 Q. Would you look in the transcript, please, at
18 page 23, beginning at line 22. Are you with me? Page
19 23, line 22?

20 A. Okay.

21 Q. Were you asked and did you answer:

22 "QUESTION: Do you know why the lead time in
23 1999 was longer than in 1997?

24 "ANSWER: IPC increased their customer base.

25 So they had additional customers that they did not have

1 in 1997."

2 Was that your testimony?

3 A. Yes, it was.

4 Q. You mentioned in answer to one of Mr. Carney's
5 questions that Klor Con M20 has been on back order for
6 six months, right?

7 A. Yes.

8 Q. But you're continuing to sell Klor Con M20, are
9 you not?

10 A. Yes.

11 Q. You were describing some additions in Upsher's
12 Building B, and you referred to pallet racking. Is
13 that essentially shelving on --

14 A. Yes.

15 Q. -- which you place pallets that have boxes of
16 bottles of Klor Con M?

17 A. Yes, that's what I was referring to.

18 Q. You mentioned that the launch team began the --
19 this is the Klor Con M20 launch team -- began its
20 efforts in May of 1999, so in 19 -- in the latter half
21 of 1997 and 1998, Upsher wasn't working on the launch
22 of Klor Con M20, was it?

23 A. That is correct.

24 MS. BOKAT: May I have just one moment, Your
25 Honor?

1 JUDGE CHAPPELL: Yes, only one moment, though,
2 not two.

3 MS. BOKAT: And you're counting.

4 JUDGE CHAPPELL: That's right.

5 (Counsel conferring).

6 MS. BOKAT: Whether or not my moment is up, I
7 have no further cross, Your Honor.

8 JUDGE CHAPPELL: Thank you. I have a couple
9 questions that -- maybe let me ask mine before you
10 redirect.

11 MR. CARNEY: Surely, Your Honor.

12 JUDGE CHAPPELL: Did I hear you talk about
13 expiration dates?

14 THE WITNESS: Yes.

15 JUDGE CHAPPELL: And you said they're two
16 years?

17 THE WITNESS: Yes.

18 JUDGE CHAPPELL: That two years is -- did I
19 hear you say that it's always two years?

20 THE WITNESS: Well, it's not always two years,
21 but if you put the bottles in a stability chamber
22 that's got high temperature and high humidity for three
23 months, that represents two years at room temperature,
24 so you can go ahead and you can start selling your
25 product with the two-year expiration dating.

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1 It's my understanding, and I'm not in
2 regulatory, but it's my understanding that in order to
3 get longer than two years, you have to have realtime.
4 So, in other words, in order to get three years
5 expiration dating, you have to have that bottle sitting
6 at room temperature for three years, then test it, make
7 sure it meets all of your specifications, and then you
8 can start using a three-year expiration date.

9 JUDGE CHAPPELL: Okay, that -- but that
10 expiration date, that doesn't have anything to do with
11 the efficacy of the drug, does it? It's just a
12 two-year random date.

13 THE WITNESS: Well, I wouldn't say that. Many
14 drugs degrade over time, so that if you have product
15 that's past your expiration date, it could be
16 subpotent, and you wouldn't have all of the active
17 ingredient available in the drug.

18 JUDGE CHAPPELL: Is the expiration date similar
19 for non-U.S. markets, say Latin America?

20 THE WITNESS: You know, I --

21 JUDGE CHAPPELL: Not your bailiwick?

22 THE WITNESS: No, I'm not familiar with that at
23 all.

24 JUDGE CHAPPELL: Okay, thank you, that's all.
25 Redirect?

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1 MR. CARNEY: Thank you, Your Honor.

2 REDIRECT EXAMINATION

3 BY MR. CARNEY:

4 Q. Is the expiration date like on milk, is that a
5 sell-by date?

6 A. I think it is. You know, I'm not -- I'm not
7 sure.

8 Q. Okay. In 1997, no launch team had been
9 established for Klor Con M. Is that right?

10 A. That's correct.

11 Q. And Upsher-Smith did not have approval for Klor
12 Con M20 in 1997, right?

13 A. Correct.

14 Q. In 1997, did you run any validation batches for
15 the Klor Con M product?

16 A. No.

17 Q. And in 1997, you did not make any payment to
18 IPC to reserve time for commercial batch. Is that
19 right?

20 A. That is correct.

21 Q. And that was because Mr. Kralovec told you not
22 to commit the \$300,000 it would have required?

23 A. The -- it would have required \$300,000 for the
24 entire month, which in my e-mail was reserved for some
25 launch quantities.

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1 Q. And in May of 1997, would IPC have given you an
2 extension to May 21 if you had not committed the
3 \$300,000?

4 A. George Tomaich had told me that he would try to
5 hold it open, but he couldn't make any promises, and a
6 few days later, we basically told him that we were not
7 going to run anything.

8 Q. Would an extension to May 21 to hold open
9 August have made any difference to Upsher-Smith at that
10 time as far as what its decision was on May 21?

11 MS. BOKAT: Objection, speculation.

12 JUDGE CHAPPELL: I'll sustain that without more
13 foundation.

14 MR. CARNEY: Yes, Your Honor.

15 BY MR. CARNEY:

16 Q. You were considering making -- asking for an
17 extension to May 21 as far as keeping open the August
18 time period. Is that right?

19 A. That is correct.

20 Q. Did anything change between May 15 and May 21
21 as far as whether you would have been willing to commit
22 or Upsher-Smith would have been willing to commit
23 \$300,000 to keep August open?

24 A. No, I don't believe so. Again, I was told by
25 Paul Kralovec not to commit any funds at all to any

1 Klor Con M production at IPC.

2 Q. Do you recall on cross exam Ms. Bokar asked you
3 about IPC's annual capacity in terms of tablets?

4 A. Yes.

5 Q. And you testified that in 1997, IPC had other
6 clients beside Upsher-Smith?

7 A. Yes.

8 Q. Based on your discussions with IPC in 1997,
9 would it have been -- would they have been willing to
10 dedicate their full annual capacity to Upsher-Smith?

11 A. No.

12 Q. And sir, you testified on direct that you did
13 do validation batches for the 2001 launch at the 400
14 kilogram batch level?

15 A. Yes.

16 Q. And did you testify also on direct that they
17 were so old by the time of the September launch that
18 they had to be "scrapped"?

19 A. Yes.

20 MR. CARNEY: That's all, Your Honor.

21 JUDGE CHAPPELL: Any questions?

22 MS. BOKAR: No, thank you, Your Honor.

23 MR. NIELDS: No, Your Honor, thank you.

24 JUDGE CHAPPELL: Thank you, Mr. Gould. You are
25 excused.

1 MR. CURRAN: Your Honor, may we call our final
2 witness of the day?

3 JUDGE CHAPPELL: Yes, you may.

4 MR. CURRAN: Your Honor, at this time we call
5 Robert Clark, and Mr. Carney will handle this
6 examination as well. Thank you.

7 MS. BOKAT: Your Honor, I have an objection to
8 this witness being called. He was never listed on
9 Upsher's witness list. We were informed that he might
10 appear to authenticate a tape.

11 MR. CARNEY: Your Honor, if I may briefly
12 address that, Upsher-Smith's final witness list of
13 December 14th, 2001 lists Mr. Clark on the front page.
14 It says, "The only changes Upsher-Smith wishes to make
15 to the earlier list are that it does not intend to call
16 Mr. Michael Jaharis of Kos Pharmaceuticals and that it
17 may call Bob Clark of Upsher-Smith to authenticate and
18 describe a videotape, the existence of which became
19 known in October. Both of these changes were
20 communicated to complaint counsel in writing in
21 October, and Mr. Clark was offered for deposition."

22 MS. BOKAT: Well, if his purpose is to
23 authenticate the tape, I'd be willing to stipulate to
24 the authenticity.

25 JUDGE CHAPPELL: Well, is that all you advised

1 the Government that he was going to do? That's what I
2 heard.

3 MR. CARNEY: We -- actually, in our October
4 letter, we advised them that he would authenticate and
5 describe that tape.

6 JUDGE CHAPPELL: What do you mean by "describe
7 the tape"?

8 MR. CARNEY: Let me explain, Your Honor. We
9 put in two identified videotapes of the construction
10 work that was needed to be done at Upsher-Smith, and
11 Mr. Clark was involved with overseeing that
12 construction. We have since, for the purpose of a
13 demonstrative, boiled it down to a short DVD with about
14 20 short tracks ranging from 10 seconds to maybe two
15 minutes, that he would just simply say, this is what is
16 being depicted in this -- in this track, this is what
17 construction is going on at this time, and that's how
18 we would propose to go forward.

19 MS. BOKAT: It seems to me that Mr. Carney has
20 just described the tape for us. I'm willing to
21 stipulate authenticity. He's described the tape. If
22 they want to run the tape, fine, but I don't see that
23 we need testimony from Mr. Clark.

24 JUDGE CHAPPELL: Did you provide any of the
25 description that he's going to give other than what's

1 depicted on the video?

2 MR. CARNEY: We have not provided any of the
3 description that he would give. We did in October
4 offer him for deposition.

5 JUDGE CHAPPELL: Okay, read to me again what
6 notice you served on the opposition regarding this
7 witness.

8 MR. CARNEY: Yes, Your Honor. I've got here,
9 and unfortunately, this is an unsigned version I've put
10 up on the ELMO of the letter that we sent on October 19
11 when we sent the videotape over. The second paragraph,
12 "The videotaping was done under the direction of
13 Upsher-Smith employee Bob Clark. If we use these tapes
14 at trial, we may use an affidavit or testimony of Mr.
15 Clark to authenticate the tapes. Please let us know
16 whether you would like to depose Mr. Clark, as he may
17 be available next week in Minnesota before or after the
18 United Healthcare deposition there."

19 JUDGE CHAPPELL: Is this Mr. Clark?

20 MR. CARNEY: This is Mr. Clark.

21 JUDGE CHAPPELL: Well, the way I see this, the
22 plain language, the other side was informed only that
23 he was going to authenticate. So, if they stipulate
24 authentication, then he doesn't testify. That's my
25 ruling.

1 MR. CARNEY: Yes, Your Honor.

2 JUDGE CHAPPELL: You can play the tape -- you
3 have got a stipulation as to its authenticity -- if you
4 want to. You don't have to accept the stipulation.
5 The stipulation takes both sides. If you want him to
6 authenticate only, we can do that, but I'm not allowing
7 him to go beyond authenticity.

8 MR. CARNEY: Yes, Your Honor, I understand
9 that. I guess what we would do at this time, then, is
10 we would move into evidence USX 711, which is the
11 videotapes, and then --

12 MR. CURRAN: Can I interrupt for a second?

13 MR. CARNEY: Certainly.

14 MR. CURRAN: Your Honor, we propose to use the
15 witness to authenticate the tape before we show it, all
16 right? In other words, we decline complaint counsel's
17 proposal, if that's what they're doing, stipulating to
18 the admissibility of this tape. We want to lay the
19 foundation for the tape and then show it to Your Honor.

20 JUDGE CHAPPELL: Okay, but I'm giving you a
21 pretty tight rein here. You don't have a lot of room
22 to dance, because the opposition was notified that he's
23 an authentication witness only, and I don't see
24 anything about description, and they were offered to
25 depose him on authentication. I'm going by what you

1 advised the opposition.

2 MR. CARNEY: Very good, Your Honor.

3 JUDGE CHAPPELL: So, if you want to refuse to
4 stipulate and put him on for authentication, then I'll
5 allow it.

6 MS. BOKAT: May I request one clarification?
7 Mr. Carney has referred to USX 711 and described it as
8 a videotape. We were actually given two things. One
9 was a videotape that came in the fall, and then this
10 week we got a DVD, and I believe they're different.
11 The DVD is excerpts, and I'm not clear whether Mr.
12 Carney is offering the videotape or the DVD.

13 MR. CARNEY: Your Honor, we're offering the
14 videotapes in their full length that were created by
15 Upsher-Smith while they were doing the construction to
16 be offered into evidence, and rather than subject the
17 Court to sitting through the two videotapes at this
18 time, we have prepared a demonstrative DVD which is
19 just selected portions of that full length type.

20 JUDGE CHAPPELL: So, you are offering the full
21 length tape plus an excerpt from that tape?

22 MR. CARNEY: That's basically -- the DVD is an
23 excerpt, a more convenient way to show it in the
24 courtroom than to fast forward through a tape.

25 JUDGE CHAPPELL: Okay, and you're representing

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1 that whatever's in the DVD is taken from the tapes that
2 were supplied?

3 MR. CARNEY: Absolutely, Your Honor, yes, it's
4 a summary.

5 JUDGE CHAPPELL: Is that clarified?

6 MS. BOKAT: Thank you, yes.

7 JUDGE CHAPPELL: Okay, then I'll need to swear
8 the witness.

9 Raise your right hand, please.
10 Whereupon--

11 ROBERT CLARK
12 a witness, called for examination, having been first
13 duly sworn, was examined and testified as follows:

14 JUDGE CHAPPELL: Thank you, have a seat.
15 State your full name for the record, please.

16 THE WITNESS: My name is Robert Clark.

17 DIRECT EXAMINATION

18 BY MR. CARNEY:

19 Q. Mr. Clark, by whom are you currently employed?

20 A. Upsher-Smith Laboratories.

21 Q. And when did you start with Upsher-Smith?

22 A. In 1995.

23 Q. And what was your --

24 MS. BOKAT: Objection, Your Honor. If he's
25 authenticating the tape, this seems to me to go way

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1 beyond authentication of the tape. We are going now
2 into his employment history.

3 MR. CARNEY: Your Honor, I am going to
4 establish that Mr. Clark is the director of plant
5 operations, that the construction falls within his
6 responsibility, and that he was responsible for
7 overseeing the videotape of the construction.

8 JUDGE CHAPPELL: In other words, he's seen this
9 and it is what it appears to be, because that's all I
10 need.

11 MR. CARNEY: I can do it that way, too, Your
12 Honor, if that's all you need.

13 JUDGE CHAPPELL: Well, I will allow you to
14 place him, who he is, where he works and how he is
15 going to verify that this is what it appears to be.
16 I'll allow that. I suppose I'm sustaining the
17 objection with the conditions I've put on the
18 testimony.

19 MR. CARNEY: Yes, Your Honor.

20 BY MR. CARNEY:

21 Q. Mr. Clark, I've got here three videotapes which
22 are marked as USX 711, labeled Upsher-Smith
23 Construction Footage, one of three, two of three and
24 three of three. Have you viewed these videos?

25 A. Yes, I have.

1 Q. And are these videos of the construction work
2 that was done at Upsher-Smith for the additions for the
3 Klor Con M20 line?

4 A. Yes, they are.

5 Q. And are they an accurate representation of the
6 construction work that was done at that time?

7 A. Yes, they are.

8 Q. And I'm going to show you what has been marked
9 for identification purposes as USX 1558, Upsher-Smith
10 Construction Footage DVD. Have you viewed this DVD?

11 A. Yes, I have.

12 Q. And is this DVD excerpts of the videotape in
13 USX 711?

14 A. Yes.

15 Q. And does it accurately represent the
16 construction work that was done at Upsher-Smith on the
17 Klor Con M addition?

18 A. Yes, it does.

19 MR. CARNEY: Your Honor, at this time we move
20 into evidence USX 711.

21 MS. BOKAT: No objection.

22 MS. SHORES: No objection, Your Honor.

23 JUDGE CHAPPELL: What about the other three?

24 MR. CARNEY: These three -- I'm sorry, Your
25 Honor, USX 711 is these three tapes collectively.

1 JUDGE CHAPPELL: Okay. And then what is -- is
2 there an exhibit number on the DVD?

3 MR. CARNEY: Yes, Your Honor, there is. It's
4 USX 1558.

5 JUDGE CHAPPELL: Are you not offering that?

6 MR. CARNEY: I was going to get -- try and get
7 711 in first and then move to 1558. I would move for
8 1558 into evidence as well, then.

9 JUDGE CHAPPELL: Any objection?

10 MS. BOKAT: No, Your Honor.

11 MS. SHORES: No objection, Your Honor.

12 JUDGE CHAPPELL: Was the first one 711?

13 MR. CARNEY: The first one is USX 711, and the
14 second one is USX 1558.

15 JUDGE CHAPPELL: Okay, USX 711 and USX 1558 are
16 admitted.

17 (USX Exhibit Numbers 711 and 1558 were admitted
18 into evidence.)

19 MR. CARNEY: Okay, at this time, Your Honor,
20 then we would just proceed to show tracks of the DVD,
21 and pursuant to your ruling, that would be without any
22 description by Mr. Clark.

23 JUDGE CHAPPELL: Okay. Unless Ms. Bokat has
24 any cross, then we can excuse the witness.

25 MS. BOKAT: I don't think I have any -- whoops,

1 excuse me.

2 (Counsel conferring.)

3 MS. BOKAT: I don't anticipate any cross, Your
4 Honor.

5 JUDGE CHAPPELL: The witness is excused. The
6 tape's already admitted.

7 MR. CARNEY: Thank you, Your Honor.

8 JUDGE CHAPPELL: Thank you, sir.

9 (Discussion off the record.)

10 JUDGE CHAPPELL: The record will contain the
11 exhibits that have just been admitted; however, if you
12 need a word-for-word transcript of what's on this
13 video, you're going to need to submit that to be part
14 of the record as another exhibit.

15 MR. CARNEY: Okay, thank you, Your Honor.

16 All right, we will start with the videotape.

17 JUDGE CHAPPELL: And before you would submit
18 something like that, and it's your choice, let's see
19 that no one else objects to it, because we have a
20 stipulation and we have a foundation laid, so perhaps
21 you'll need to have a certified transcript to remedy
22 any objections. It's your choice.

23 MR. CURRAN: Your Honor, if I could just
24 apologize for the disruption and awkwardness in the
25 presentation of this videotape. We did not know that

1 complaint counsel was going to pose an objection as to
2 this. We got no response to our October letter or to
3 our December final witness list. So, thank you for
4 bearing with us.

5 JUDGE CHAPPELL: Sure, and I just want to make
6 clear, it -- to me, this is a discovery issue, and I'll
7 go right down the line, when I see -- just like I did.
8 When I see notice was given to the other side, then
9 I'm -- I follow the rules, and I'm limiting this to
10 what I thought they were notified of. It was their
11 choice whether to object or not or whether to depose
12 the person or not, but I'm trying to be as fair as I
13 can and let things in the record that I think need to
14 be so that everybody gets a fair hearing.

15 MR. CARNEY: Thank you, Your Honor.

16 JUDGE CHAPPELL: Proceed.

17 (DVD, USX Exhibit 1558, played for the Court.)

18 JUDGE CHAPPELL: Before that starts, if you
19 choose to submit a certified transcript, are you making
20 a note of which portions you are playing the Court?

21 MR. CARNEY: Yes, sir, we have got it noted
22 here, yes.

23 JUDGE CHAPPELL: Thank you.

24 (DVD, USX Exhibit 1558, continued for the
25 Court.)

1 JUDGE CHAPPELL: Is there a way you can feed
2 that onto the big screens for the spectators?

3 MR. CARNEY: I didn't realize it wasn't there.

4 I'm sure there is, Your Honor, but we're not
5 sure how to do that at this time.

6 JUDGE CHAPPELL: Okay, just so we don't have a
7 riot, it's okay with me. Everybody behind you is lost
8 right now.

9 (DVD, USX Exhibit 1558, continued for the Court
10 to completion.)

11 MR. CARNEY: Your Honor, that's the extent of
12 the videotape. I submit it would have been more
13 interesting with the narration but certainly more
14 efficient to go through it this way.

15 That's I think all we have for today with the
16 Upsher-Smith witnesses, Your Honor.

17 JUDGE CHAPPELL: Okay, thank you.

18 Anything further today?

19 MR. CURRAN: No, Your Honor.

20 MR. NIELDS: No, Your Honor.

21 MS. BOKAT: No, Your Honor.

22 JUDGE CHAPPELL: Okay, I have verified that I
23 have a hearing at 3:00 on Monday in another matter.
24 So, we will knock off no later than 2:45 on Monday, but
25 we will start at 9:30 Monday. We are adjourned until

1 then. Thank you.

2 (Whereupon, at 5:00 p.m., the hearing was
3 adjourned.)

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For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: FEBRUARY 22, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 2/25/02

13

14

15

16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

19

20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

23

24

25 DIANE QUADE

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